

Statutory Changes to Pharmacy Law

Unless otherwise noted, the provisions take effect January 1, 2019.

Business and Professions Code Changes

Section 4008 of the Business and Professions Code is amended to read:

(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 his or her 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, he or she may make an arrest although the violation or suspected violation did not occur in his or her 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 his or her 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 his or her 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 or 4119.1.

(g) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 4008 of the Business and Professions Code is amended to read:

(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 his or her 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, he or she may make an arrest although the violation or suspected violation did not occur in his or her 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 his or her 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 his or her 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).

(h) This section shall become operative on July 1, 2019.

Section 4017.3 is added to the Business and Professions Code to read:

(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.

(d) This section shall become operative on July 1, 2019.

Section 4021.5 of the Business and Professions Code is amended to read:

(a) “Correctional pharmacy” means a pharmacy, licensed by the board, located within a correctional facility for the purpose of providing drugs to a correctional clinic, as defined in Section 4187, and providing pharmaceutical care to inmates of the correctional facility.

(b) As part of its pharmaceutical care, a correctional pharmacy may dispense or administer medication pursuant to a chart order, as defined in Section 4019, or other valid prescription consistent with this chapter.

Section 4052.2 of the Business and Professions Code is amended to read:

(a) Notwithstanding any other law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, a licensed clinic in which there is a 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, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber’s order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient’s treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient’s treating prescriber, or enter the

appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

Section 4057 of the Business and Professions Code is amended to read:

(a) Except as provided in Section 4006, subdivision (d) of Section 4081, Section 4240, subdivisions (t) and (u) of Section 4301, and Section 4342, this chapter does not apply to the retail sale of nonprescription drugs that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(b) This chapter does not apply to specific dangerous drugs and dangerous devices listed in board regulations, where the sale or furnishing is made to any of the following:

(1) A physician, dentist, podiatrist, pharmacist, medical technician, medical technologist, optometrist, or chiropractor holding a currently valid and unrevoked license and acting within the scope of his or her profession.

(2) A clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(3) A correctional clinic, as defined in Section 4187, holding a currently valid and unrevoked license or permit under Article 13.5 (commencing with Section 4187).

(c) This chapter shall not apply to a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, when it purchases, stores, furnishes, or transports specific dangerous drugs and dangerous devices listed in board regulations in compliance with applicable law and regulations including:

(1) Dangerous devices described in subdivision (b) of Section 4022, as long as these dangerous devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

(2) Hypodermic needles and syringes.

(3) Irrigation solutions of 50 cubic centimeters or greater.

(d) This chapter does not apply to the storage of devices in secure central or ward supply areas of a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, or pursuant to Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(e) This chapter does not apply to the retail sale of vitamins, mineral products, or combinations thereof or to foods, supplements, or nutrients used to fortify the diet of humans or other animals or poultry and labeled as such that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state labeling requirements.

(f) This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of nursing. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of nursing for purposes of this subdivision are those schools recognized as training facilities by the California Board of Registered Nursing.

Section 4062 of the Business and Professions Code is amended to read:

(a) Notwithstanding Section 4059 or any other ~~provision of law~~, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any

other ~~provision of~~ law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed ~~pharmacist~~ pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a ~~pharmacist~~ pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

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

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

Section 4064 of the Business and Professions Code is amended to read:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(g) During a proclaimed state of emergency, nothing in either this section or any other provision of this chapter prohibits a pharmacist, a clinic licensed under Section 4180, or a mobile pharmacy or clinic described in subdivision (c) of Section 4062 from refilling a prescription if the prescriber is unavailable, or if after a reasonable effort has been made, the pharmacist, clinic, or mobile pharmacy is unable to contact the prescriber.

Section 4076.7 is added to the Business and Professions Code to read:

In addition to the requirements of Sections 4076 and 4076.5, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction."

Section 4079 is added to the Business and Professions Code to read:

(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is inconsistent with this section is void and unenforceable.

(e) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

Section 4079.5 is added to the Business and Professions Code to read:

(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is entered into on or after January 1, 2019, that is inconsistent with this section is void and unenforceable.

(e) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

Section 4081 of the Business and Professions Code is amended to read:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

Section 4105.5 of the Business and Professions Code is amended to read:

(a) For purposes of this section, an “automated drug delivery system” has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:

(1) Use of the automated drug delivery system is consistent with legal requirements.

(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.

(4) The pharmacy license is unexpired and not subject to disciplinary conditions.

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 4106.5 is added to the Business and Professions Code to read:

(a) For purposes of this section, the following terms shall have the following meanings:

(1) "Pharmacy" does not include a pharmacy that meets both of the following requirements:

(A) It is owned and operated by a person or persons in which the majority of the beneficial interest, as well as management and control, resides with at least one board-licensed pharmacist, as that term is defined in Section 4036, that exclusively oversees the operations of the pharmacy.

(B) The owner and operator with the beneficial interest, management, and control described in subparagraph (A) owns, operates, and has management and control of no more than four pharmacies.

(2) "Safe storage products" means a device or product made with the purpose of storing prescription medications that includes a locking mechanism that is accessible only by the designated patient with a passcode, alphanumeric code, key, or by another secure mechanism. A safe storage product includes, but is not limited to, medicine lock boxes, locking medicine cabinets, locking medication bags, and prescription locking vials.

(3) "Schedule II, III, or IV controlled substances" means any substance defined as a Schedule II, III, or IV controlled substance in Sections 11055, 11056, and 11057 of the Health and Safety Code.

(b) A pharmacy that dispenses Schedule II, III, or IV controlled substances shall display safe storage products in a place on the building premises that is located close to the pharmacy.

(c) (1) The board shall assess a fine in an amount to be determined by the board for a violation of this section.

(2) Notwithstanding paragraph (1), the board may choose not to take administrative action against a pharmacy if it determines that compliance with this section would create a financial hardship on the pharmacy or that the pharmacy is temporarily out of stock of safe storage products.

(d) Section 4321 shall not apply to a violation of this section.

(e) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

Section 4113.5 is added to the Business and Professions Code to read:

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Section 4118.5 is added to the Business and Professions Code to read:

(a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patient under the following conditions:

(1) The hospital has more than 100 beds.

(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.

(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:

(1) The hospital pharmacy has a quality assurance program to monitor competency.

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.

(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.

(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.

(e) This section shall not apply to the State Department of State Hospitals.

(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

Section 4119.1 of the Business and Professions Code is amended to read:

(a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) This section shall not be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 4119.9 is added to the Business and Professions Code to read:

Notwithstanding any other law, a pharmacy, wholesaler, or manufacturer may furnish naloxone hydrochloride or other opioid antagonists to a law enforcement agency if both of the following are met:

(a) The naloxone hydrochloride or other opioid antagonist is furnished exclusively for use by employees of the law enforcement agency who have completed training, provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists.

(b) Records regarding the acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished pursuant to this section shall be maintained by the law enforcement agency for a period of three years from the date the records were created. The law enforcement agency shall be responsible for monitoring the supply of naloxone hydrochloride or other opioid antagonists and ensuring the destruction of expired naloxone hydrochloride or other opioid antagonists.

The following section is effective as of September 21, 2018.

Section 4119.11 is added to the Business and Professions Code to read:

(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 in the event 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. The review shall be conducted on a monthly basis by a pharmacist and 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 an annual 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.

Section 4126.5 is added to the Business and Professions Code to read:

(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

(b) Notwithstanding subdivision (a), or any other law, a clinic licensed under Section 4180 may furnish dangerous drugs to any of the following during a proclaimed state of emergency:

(1) Another clinic or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A clinic furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(2) A patient pursuant to a prescription or as otherwise authorized by law.

(3) A health care provider that is not a clinic but that is authorized to purchase dangerous drugs.

(4) To another clinic under common control, including a mobile clinic, as described in subdivision (c) of Section 4062.

~~(b)~~ (c) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

~~(c)~~ (d) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

~~(d)~~ (e) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

Section 4186 of the Business and Professions Code is amended to read:

(a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic 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 drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and 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.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an “automated drug delivery system” means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery 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.

(i) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 4186 is added to the Business and Professions Code to read:

(a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic 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 drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient’s profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and 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.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(h) This section shall become operative on July 1, 2019.

Section 4187 is added to the Business and Professions Code to read:

For purposes of this article the following terms shall have the following meanings:

(a) “Correctional clinic” means a primary care clinic, as referred to in subdivision (b) of Section 1206 of the Health and Safety Code, conducted, maintained, or operated by the state to provide health care to eligible patients of the Department of Corrections and Rehabilitation.

(b) "Chief executive officer" means the highest ranking health care administrator at a correctional institution.

(c) "Chief medical executive" means a physician and surgeon acting in the capacity of medical director within the correctional institution.

(d) "Chief nurse executive" means the highest ranking nurse within the correctional institution.

(e) "Licensed correctional clinic" means a correctional clinic that is licensed pursuant to this article.

(f) "Supervising dentist" means the highest ranking dentist within the correctional institution.

Section 4187.1 is added to the Business and Professions Code to read:

(a) Notwithstanding any other provision of this chapter, a correctional clinic licensed by the board under this article may obtain drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board under this article within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either:

(1) The direction of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.

(2) An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

(b) The dispensing or administering of drugs in a correctional clinic may be performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. The dispensing of drugs in a correctional clinic shall only be performed by a physician and surgeon, a dentist, a pharmacist, or other person lawfully authorized to dispense drugs. Medications dispensed to patients that are to be kept on the patient's person for use shall meet the labeling requirements of Section 4076 and all recordkeeping requirements of this chapter.

(c) A correctional clinic shall keep records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(d) (1) A correctional clinic shall not be entitled to the benefits of this section until it has obtained a license from the board.

(2) A separate license shall be required for each correctional clinic location and shall not be transferrable.

(3) A correctional clinic's location and address shall be identified by correctional institution and building within that correctional institution.

(4) A clinic shall notify the board in advance of any change in the clinic's address on a form furnished by the board.

Section 4187.2 is added to the Business and Professions Code to read:

(a) The policies and procedures to implement the laws and regulations of this article within a correctional clinic shall be developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. Prior to the issuance of a correctional clinic license by the board, an acknowledgment shall be signed by the correctional facility pharmacist-in-charge servicing that institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer.

(b) (1) The chief executive officer shall be responsible for the safe, orderly, and lawful provision of pharmacy services. The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive.

(2) A licensed correctional clinic shall notify the board within 30 days of any change in the chief executive officer on a form furnished by the board.

(c) A correctional facility pharmacist shall be required to inspect the clinic at least quarterly.

Section 4187.3 is added to the Business and Professions Code to read:

A Schedule II, III, IV, or V controlled substance may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

Section 4187.4 is added to the Business and Professions Code to read:

The board shall have the authority to inspect a correctional clinic at any time in order to determine whether a correctional clinic is, or is not, operating in compliance with this article.

Section 4187.5 is added to the Business and Professions Code to read:

(a) An automated drug delivery system, as defined in subdivision (h), may be located in a correctional clinic licensed by the board under this article. If an automated drug delivery system is located in a correctional clinic, the correctional clinic shall implement the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained either in electronic form or paper form at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed and if, in the prescriber's professional judgment, delay in therapy may cause patient harm, a medication may be removed from the automated drug delivery system and administered or furnished to a patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be

removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of medication from an automated drug delivery system shall be documented and provided to the correctional pharmacy when it reopens.

(c) Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division who is lawfully authorized to perform that task.

(d) The stocking of an automated drug delivery system shall be performed by either:

(1) A pharmacist.

(2) An intern pharmacist or pharmacy technician, acting under the supervision of a pharmacist.

(e) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the correctional clinic. The review shall be conducted on a monthly basis by a pharmacist and 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.

(f) The automated drug delivery system shall be operated by a licensed correctional pharmacy. Any drugs within an automated drug delivery system are considered owned by the licensed correctional pharmacy until they are dispensed from the automated drug delivery system.

(g) Drugs from the automated drug delivery system in a correctional clinic shall only be removed by a person lawfully authorized to administer or dispense the drugs.

(h) For purposes of this section, an “automated drug delivery system” means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery 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.

Section 4203.6 is added to the Business and Professions Code to read:

(a) Each application for a license as a correctional clinic under Article 13.5 (commencing with Section 4187) shall be made on a form furnished by the board. The application form shall contain the name and address of the applicant, the name of its chief executive officer, as defined in Section 4187, and the name of the pharmacist-in-charge of the correctional pharmacy that provides drugs to the clinic.

(b) Upon the filing of the application and payment of the fee prescribed in Section 4400, where applicable, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for licensure. The board shall also determine whether this article has been complied with and shall investigate all matters directly related to the issuance of the license. The board shall not, however, investigate any matters connected with the operation of a premises, including, but not limited to, operating hours, parking availability, or operating noise, except those matters relating to the furnishing or dispensing of drugs

or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made does not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under this article, the executive officer of the board shall issue a license authorizing the correctional clinic to which it is issued to obtain drugs pursuant to Article 13.5 (commencing with Section 4187). The license shall be renewed annually on or before December 31 of each year upon payment of the renewal fee prescribed in Section 4400, if applicable. A license shall not be transferable.

Section 4301 of the Business and Professions Code is amended to read:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct ~~shall include,~~ includes, but is not limited to, any of the following:

(a) Procurement of a license by fraud or misrepresentation.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medical program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not

to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, “long-term care facility” ~~shall have~~ has the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device’s manufacturer or the manufacturer’s authorized ~~distributors~~ distributor as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer’s authorized distributors as identified in Section 4160.5.

Section 4400 of the Business and Professions Code is amended to read:

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars (\$665) and may be increased to nine hundred thirty dollars (\$930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars (\$260) and may be increased to two hundred eighty-five dollars (\$285).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars (\$195) and may be increased to two hundred fifteen dollars (\$215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars (\$360) and may be increased to five hundred five dollars (\$505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars (\$170) and may be increased to two hundred forty dollars (\$240). The fee for a hypodermic license renewal shall be two hundred dollars (\$200) and may be increased to two hundred eighty dollars (\$280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars (\$165) and may be increased to two hundred thirty dollars (\$230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars (\$520) for each license and may be increased to five hundred seventy dollars (\$570). The annual fee for renewal of the license shall be three hundred twenty-five dollars (\$325) for each license and may be increased to three hundred sixty dollars (\$360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars (\$435) and may be increased to six hundred ten dollars (\$610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars (\$330) and may be increased to four hundred sixty dollars (\$460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars (\$1,645) and may be increased to two thousand three hundred five dollars (\$2,305). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to one thousand eight hundred fifty-five dollars (\$1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to three thousand three hundred thirty-five dollars (\$3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to three thousand one hundred eighty dollars (\$3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars (\$820) and may be increased to one thousand one hundred fifty dollars (\$1,150). The annual renewal of the license shall be eight hundred five dollars (\$805) and may be increased to one thousand one hundred twenty-five dollars (\$1,125).

(z) This section shall become operative on July 1, 2017. The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars (\$325) and may be increased to three hundred sixty dollars (\$360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250). The fee for the annual renewal of

the license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250).

Article 25 (commencing with section 4427) is added to Chapter 9 of Division 2 of, the Business and Professions Code to read:

Article 25. Automated Drug Delivery System

Section 4427 is added to the Business and Professions Code to read:

As used in this article, “drugs” or “dangerous drugs” shall have the same meaning as “dangerous drug” as provided in Section 4022 and “devices” or “dangerous devices” shall have the same meaning as “dangerous device” as provided in Section 4022.

Section 4427.1 is added to the Business and Professions Code to read:

An ADDS shall not be installed or operated in California unless it meets the requirements of this article.

Section 4427.2 is added to the Business and Professions Code to read:

(a) An ADDS installed, leased, owned, or operated in California shall be licensed by the board.

(b) An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

(c) A separate application and license shall be required for each ADDS.

(d) An ADDS license shall only be issued when the following conditions are met:

(1) Use of the ADDS is consistent with legal requirements.

(2) The proposed location for installation of the ADDS meets the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

(3) The pharmacy’s policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(4) The pharmacy’s policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

(e) Prior to issuance of the license, the board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of the ADDS shall require a new application for licensure. Replacement of an ADDS shall require notification to the board within 30 days.

(f) The ADDS 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 ADDS license may be submitted to the board.

(g) The holder of an ADDS license shall advise the board in writing within 30 days if use of the ADDS is discontinued.

(h) The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.

(i) An AUDES operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section if the licensed hospital pharmacy owns or leases the AUDES and owns the dangerous drugs and dangerous devices in the AUDES. The AUDES shall comply with all other requirements for an ADDS in this article. The licensed hospital pharmacy shall maintain a list of the locations of each AUDES it operates and shall make the list available to the board upon request.

(j) An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

Section 4427.3 is added to the Business and Professions Code to read:

(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.

(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.

Section 4427.4 is added to the Business and Professions Code to read:

(a) The ADDS shall be owned or leased by the pharmacy holding the license for the ADDS.

(b) Each ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

(c) An ADDS shall be considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and shall be subject to inspection pursuant to Section 4008.

(d) Drugs and devices stored in an ADDS shall be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and drugs and devices dispensed from the ADDS shall be considered to have been dispensed by that pharmacy.

(e) (1) The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

(2) Access to the ADDS shall be controlled and tracked using an identification or password system or biosensor.

(3) The ADDS shall make a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system.

(f) If drugs or devices are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs and devices shall be stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

Section 4427.5 is added to the Business and Professions Code to read:

Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to subdivision (b) of Section 4427.3.

Section 4427.6 is added to the Business and Professions Code to read:

In addition to any other requirements imposed by this article, an APDS shall additionally meet the following requirements:

(a) The pharmacy shall develop and implement, and review annually, written policies and procedures pertaining to the APDS, including all of the following:

(1) Maintaining the security of the APDS and the dangerous drugs and dangerous devices within that APDS.

(2) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.

(4) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

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

(6) Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

(b) The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established pursuant to subdivision (a).

(c) The APDS 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.

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

(e) Drugs shall be dispensed from the APDS only upon authorization by a licensed pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(f) All prescribed drugs and devices dispensed to a patient from an APDS 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.

(g) The APDS shall include a notice, prominently posted on the APDS, providing the name, address, and phone number of the pharmacy that holds the ADDS license for that APDS.

(h) The labels on all drugs and devices dispensed by the APDS shall comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(i) Any incident involving the APDS where a complaint, error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(j) An APDS may be located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice.

(k) The board shall not issue a pharmacy more than 15 ADDS licenses for APDS units. Consistent with Section 4001.1, the board, by regulation, may reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

(l) The pharmacy holding the ADDS license for an APDS shall maintain the policies and procedures developed pursuant to subdivision (a) for three years after the last date of use of that APDS.

Section 4427.7 is added to the Business and Professions Code to read:

(a) A pharmacy holding an ADDS license shall complete an annual 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.

Section 4427.8 is added to the Business and Professions Code to read:

(a) This article shall become operative on July 1, 2019.

(b) On or before January 1, 2024, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

(1) The use and dispersion of ADDS throughout the health care system.

(2) The number of ADDS inspections conducted by the board each year and the findings from the inspections.

(3) Public safety concerns relating to the use of ADDS as identified by the board.

Health and Safety Code Changes

Section 1261.6 of the Health and Safety Code is amended to read:

(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery 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) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or ~~(k)~~, (k) of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) 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.

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

(d) (1) 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.

(2) 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.

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

(1) 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.

(2) 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.

(3) 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.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

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

(2) 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.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

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

(5) 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.

(6) 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.

(7) (A) 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. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) 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:

(1) 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.

(2) 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.

(3) 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.

(h) 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. The review shall be conducted on a monthly basis by a pharmacist and 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.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 1261.6 is added to the Health and Safety Code, to read:

(a) (1) For purposes of this section and Section 1261.5, an “automated drug delivery system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery 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) For purposes of this section, “facility” means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, “pharmacy services” means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) 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.

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

(d) (1) 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.

(2) 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.

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

(1) 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.

(2) 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.

(3) 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.

(f) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

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

(2) 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.

(3) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

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

(5) 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.

(6) 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.

(7) (A) 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. Each facility using such an automated drug delivery system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel

with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) 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:

(1) 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.

(2) 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.

(3) 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.

(h) 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. The review shall be conducted on a monthly basis by a pharmacist and 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.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become operative on July 1, 2019.

Section 11055 of the Health and Safety Code is amended to read:

(a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Codeine.

(H) Ethylmorphine.

(I) (i) Hydrocodone.

(ii) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(iii) Oral liquid preparations of dihydrocodeinone containing the above specified amounts that contain, as its nonnarcotic ingredients, two or more antihistamines in combination with each other.

(iv) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(J) Hydromorphone.

(K) Metopon.

(L) Morphine.

(M) Oxycodone.

(N) Oxymorphone.

(O) Thebaine.

(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(6) Cocaine, except as specified in Section 11054.

(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:

(1) Alfentanyl.

(2) Alphaprodine.

(3) Anileridine.

(4) Bezitramide.

(5) Bulk dextropropoxyphene (nondosage forms).

(6) Dihydrocodeine.

(7) Diphenoxylate.

(8) Fentanyl.

(9) Isomethadone.

(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).

(11) Levomethorphan.

(12) Levorphanol.

(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) Khat, which includes all parts of the plant classified botanically as *Catha Edulis*, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(8) Cathinone (also known as alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone).

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital.

(2) Pentobarbital.

(3) Phencyclidines, including the following:

(A) 1-(1-phenylcyclohexyl) piperidine (PCP).

(B) 1-(1-phenylcyclohexyl) morpholine (PCM).

(C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph. The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted, submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.

(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(A) Phenylacetone. Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

Section 11056 of the Health and Safety Code is amended to read:

(a) The controlled substances listed in this section are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation ~~which~~ that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Section 1308.32 of Title 21 of the Code of Federal Regulations, and any other drug of the quantitative composition shown in that list for those drugs or ~~which~~ that is the same except that it contains a lesser quantity of controlled substances.

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation ~~which~~ that contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital or any salt thereof and one or more other active medicinal ingredients ~~which~~ that are not listed in any schedule.

(2) Any suppository dosage form containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.

(3) Any substance ~~which~~ that contains any quantity of a derivative of barbituric acid or any salt thereof.

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(11) Gamma hydroxybutyric acid, and its salts, isomers and salts of isomers, contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.~~

~~(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts. Additionally, oral liquid preparations of dihydrocodeinone containing the above specified amounts may not contain as its nonnarcotic ingredients two or more antihistamines in combination with each other.~~

~~(5)~~ (3) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~(6)~~ (4) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(7)~~ (5) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(8)~~ (6) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chlormethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.

(11) Formyldienolone.

(12) 4-Hydroxy-19-nortestosterone.

(13) Mesterolone.

(14) Methandriol.

(15) Methandrostenolone.

(16) Methenolone.

(17) 17-Methyltestosterone.

(18) Methyltrienolone.

(19) Nandrolone.

(20) Norbolethone.

(21) Norethandrolone.

(22) Normethandrolone.

(23) Oxandrolone.

(24) Oxymestrone.

(25) Oxymetholone.

(26) Quinbolone.

(27) Stanolone.

(28) Stanozolol.

(29) Stenbolone.

(30) Testosterone.

(31) Trenbolone.

(32) Human Chorionic Gonadotropin (HCG), chorionic gonadotropin (hCG), except when possessed by, sold to, purchased by, transferred to, or administered by a licensed veterinarian, or a licensed veterinarian's designated agent, exclusively for veterinary use.

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

Section 11018.5 of the Health and Safety Code is amended to read:

(a) "Industrial hemp" means a ~~fiber or oilseed crop, or both, crop~~ that is limited to types of the plant *Cannabis sativa* L. having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin produced therefrom.

(b) Industrial hemp shall not be subject to the provisions of this division or of Division 10 (commencing with Section 26000) of the Business and Professions Code, but instead shall be regulated by the Department of Food and Agriculture in accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agricultural Code, inclusive.

The following section is effective as of July 9, 2018.

Section 11150.2 is added to the Health and Safety Code to read:

(a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

(b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.

(c) This section does not apply to any product containing cannabidiol that is made or derived from industrial hemp, as defined in Section 11018.5 and regulated pursuant to that section.

Section 11158.1 is added to the Health and Safety Code to read:

(a) Except when a patient is being treated as set forth in Sections 11159, 11159.2, and 11167.5, and Article 2 (commencing with Section 11215) of Chapter 5, pertaining to the treatment of addicts, or for a diagnosis of chronic intractable pain as used in Section 124960 of this code and Section 2241.5 of the Business and Professions Code, a prescriber shall discuss all of the following with the minor, the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment before directly dispensing or issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid:

(1) The risks of addiction and overdose associated with the use of opioids.

(2) The increased risk of addiction to an opioid to an individual who is suffering from both mental and substance abuse disorders.

(3) The danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

(4) Any other information required by law.

(b) This section does not apply in any of the following circumstances:

(1) If the minor's treatment includes emergency services and care as defined in Section 1317.1.

(2) If the minor's treatment is associated with or incident to an emergency surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

(3) If, in the prescriber's professional judgment, fulfilling the requirements of subdivision (a) would be detrimental to the minor's health or safety, or in violation of the minor's legal rights regarding confidentiality.

(c) Notwithstanding any other law, including Section 11374, failure to comply with this section shall not constitute a criminal offense.

Section 11161.5 of the Health and Safety Code is amended to read:

(a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).

(5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (l) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.

(d) The department may deny a security printer application on any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

(i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or ~~e-mail~~ email within 24 hours of the theft or loss.

(l) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(m) The following violations by security printers shall be punishable pursuant to subdivision (n):

(1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.

(2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.

(3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.

(n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):

(1) For a first violation, a fine not to exceed one thousand dollars (\$1,000).

(2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars (\$2,500) for each violation.

(3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.

(o) In order to facilitate the standardization of all prescription forms and the serialization of prescription forms with unique identifiers, the Department of Justice may cease issuing new approvals of security printers to the extent necessary to achieve these purposes. The department may, pursuant to regulation, reduce the number of currently approved security printers to no fewer than three vendors. The department shall ensure that any reduction or limitation of approved security printers does not impact the ability of vendors to meet demand for prescription forms.

Section 11162.1 of the Health and Safety Code is amended to read:

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the “Prescription is void if the number of drugs prescribed is not noted.”

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber’s order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(15) A uniquely serialized number, in a manner prescribed by the Department of Justice.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

~~(d) This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012. Within the next working day following delivery, a security printer shall submit via Web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:~~

(1) Serial numbers of all prescription forms delivered.

(2) All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms.

(3) The delivery shipment recipient names.

(4) The date of delivery.

Section 11165 of the Health and Safety Code is amended to read:

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, ~~provided that~~ if patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The Department of Justice shall, no later than July 1, 2020, adopt regulations regarding the access and use of the information within CURES. The Department of Justice shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

~~(3)~~ (4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data ~~is~~ are provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, ~~if applicable,~~ the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt ~~facility.~~ facility, if provided.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The Department of Justice may enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the Department of Justice pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the Department of Justice for interstate data sharing of prescription drug monitoring program information.

(3) Any agreement entered into by the Department of Justice for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if he or she is registered and in good standing with that state's prescription drug monitoring program.

(5) The Department of Justice shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

Section 11165.6 is added to the Health and Safety Code to read:

A prescriber shall be allowed to access the CURES database for a list of patients for whom that prescriber is listed as a prescriber in the CURES database.

Section 121349 of the Health and Safety Code is amended to read:

(a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic

needles and syringes. Authorization shall be made after consultation with the local health officer and local law enforcement leadership, and after a period of public comment, as described in subdivision (e). In making the determination, the department shall balance the concerns of law enforcement with the public health benefits. The authorization shall not be for more than two years. Before the end of the two-year period, the department may reauthorize the program in consultation with the local health officer and local law enforcement leadership.

(d) In order for an entity to be authorized to conduct a project pursuant to this chapter, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:

(1) The entity provides, directly or through referral, all of the following services:

(A) Drug abuse treatment services.

(B) HIV or hepatitis screening.

(C) Hepatitis A and hepatitis B vaccination.

(D) Screening for sexually transmitted infections.

(E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.

(F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.

(3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:

(A) Provide needles and syringe exchange services for all of its participants.

(B) Provide HIV and viral hepatitis prevention education services for all of its participants.

(C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:

(A) The total number of persons served.

(B) The total number of syringes and needles distributed, recovered, and disposed of.

(C) The total numbers and types of referrals to drug treatment and other services.

(e) If the application is provisionally deemed appropriate by the department, the department shall, at least 45 days prior to approval of the application, provide for a period of public comment as follows:

(1) Post on the department's Internet Web site the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.

(2) Send a written and an e-mail notice to the local health officer of the affected jurisdiction.

(3) Send a written and an e-mail notice to the chief of police, the sheriff, or both, as appropriate, of the jurisdictions in which the program will operate.

(f) The department shall establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to this chapter.

(g) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(h) If the department, in its discretion, determines that a state authorized syringe exchange program continues to meet all standards set forth in subdivision (d) and that a public health need exists, it may administratively approve amendments to a program's operations including, but not limited to, modifications to the time, location, and type of services provided, including the designation as a fixed site or a mobile site. The amendment approval shall not be subject to the noticing requirements of subdivision (e).

(i) The department shall have 30 business days to review and respond to the applicant's request for amendment of the authorization. If the department does not respond in writing within 30 business days the request shall be deemed denied.

Section 121349.1 of the Health and Safety Code, as added by Section 2.5 of Chapter 744 of the Statutes of 2011, is repealed.

~~121349.1.~~

~~The State Department of Public Health or a city, county, or a city and county with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes or any materials deemed by a local or state health department to be necessary to prevent the spread of communicable diseases, or to prevent drug overdose, injury, or disability during participation in an exchange project. Program participants shall not be subject to criminal prosecution for possession of needles or syringes or any materials deemed by a local or state health department to be necessary to prevent the spread of communicable diseases, or to~~

~~prevent drug overdose, injury, or disability acquired from an authorized needle and syringe exchange project entity.~~

Section 121349.2 of the Health and Safety Code, as added by Section 3.5 of Chapter 744 of the Statutes of 2011, is repealed

~~121349.2.~~

~~Local government, local health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated. (b) This section shall become inoperative on January 1, 2019, and as of that date is repealed.~~

Section 121349.3 of the Health and Safety Code, as added by Section 5 of Chapter 744 of the Statutes of 2011, is repealed.

~~121349.3.~~

~~The health officer of the participating jurisdiction shall present biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this biennial meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local health officer based on the reports to the department from service providers within the jurisdiction of that local health officer.~~

California Civil Code Changes

Section 56.06 of the Civil Code is amended to read:

(a) Any business organized for the purpose of maintaining medical information, as defined in subdivision (j) of Section 56.05, in order to make the information available to an individual or to a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage his or her information, or for the diagnosis and treatment of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(b) Any business that offers software or hardware to consumers, including a mobile application or other related device that is designed to maintain medical information, as defined in subdivision (j) of Section 56.05, in order to make the information available to an individual or a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage his or her information, or for the diagnosis, treatment, or management of a medical condition of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified

in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(c) Any business that is licensed pursuant to Division 10 (commencing with Section 26000) of the Business and Professions Code that is authorized to receive or receives identification cards issued pursuant to Section 11362.71 of the Health and Safety Code or information contained in a physician's recommendation issued in accordance with Article 25 (commencing with Section 2525) of Chapter 5 of Division 2 of the Business and Professions Code shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(d) Any business described in this section shall maintain the same standards of confidentiality required of a provider of health care with respect to medical information disclosed to the business.

(e) Any business described in this section is subject to the penalties for improper use and disclosure of medical information prescribed in this part.

Section 56.105 of the Civil Code is amended to read:

Whenever, prior to the service of a complaint upon a defendant in any action arising out of the professional negligence of a person holding a valid physician's and surgeon's certificate issued pursuant to Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, ~~or~~ a person holding a valid license as a marriage and family therapist issued pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code, a person holding a valid license as a clinical social worker issued pursuant to Chapter 14 (commencing with Section 4991) of Division 2 of the Business and Professions Code, or a person holding a valid license as a professional clinical counselor issued pursuant to Chapter 16 (commencing with Section 4999.10) of Division 2 of the Business and Professions Code, a demand for settlement or offer to compromise is made on a patient's behalf, the demand or offer shall be accompanied by an authorization to disclose medical information to persons or organizations insuring, responsible for, or defending professional liability that the certificate holder may incur. The authorization shall be in accordance with Section 56.11 and shall authorize disclosure of that information that is necessary to investigate issues of liability and extent of potential damages in evaluating the merits of the demand for settlement or offer to compromise.

Notice of any request for medical information made pursuant to an authorization as provided by this section shall be given to the patient or the patient's legal representative. The notice shall describe the inclusive subject matter and dates of the materials requested and shall also authorize the patient or the patient's legal representative to receive, upon request, copies of the information at his or her expense.

Nothing in this section shall be construed to waive or limit any applicable privileges set forth in the Evidence Code except for the disclosure of medical information subject to the patient's authorization. Nothing in this section shall be construed as authorizing a representative of any person from whom settlement has been demanded to communicate in violation of the physician-patient privilege with a treating physician, or to communicate in violation of the psychotherapist-patient privilege with a treating licensed marriage and family therapist, licensed clinical social worker, or licensed professional clinical counselor, except for the medical information request.

The requirements of this section are independent of the requirements of Section 364 of the Code of Civil Procedure.