

Statutory Changes to Pharmacy Law

Unless otherwise noted, the provisions take effect January 1, 2018

Business and Professions Code Changes

Section 4001.5 of the Business and Professions Code is repealed.

~~The Joint Committee on Boards, Commissions, and Consumer Protection shall review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage, including, but not limited to, a review of the current California pharmacist licensure examination.~~

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.

Section 4013 of the Business and Professions Code is amended to read:

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

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

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email address to the board's email notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, informing the board of the single email address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification list within 30 days of any change in the owner's email address.

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

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

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

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

(5) This subdivision shall become operative on July 1, 2017.

Section 4022.5 of the Business and Professions Code is amended to read:

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

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

Section 4022.6 is added to the Business and Professions Code, to read:

“Designated representative-reverse distributor” means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

Section 4029 of the Business and Professions Code is amended to read:

(a) “Hospital pharmacy” means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy ~~also includes~~ may include a pharmacy that ~~may be located outside of the hospital in another~~ is located in any physical plant that is regulated under ~~a hospital’s consolidated license issued pursuant to Section 1250.8~~ the license of a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) “Hospital satellite compounding pharmacy” means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Section 4034.5 is added to the Business and Professions Code, to read:

An “emergency medical services automated drug delivery system” or “EMSADDS” means an automated drug delivery system that stores and distributes drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services.

Section 4040.5 of the Business and Professions Code is amended to read:

“Reverse distributor” means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous ~~drugs~~. drugs or dangerous devices.

Section 4044.3 is added to the Business and Professions Code, to read:

(a) “Remote dispensing site pharmacy” means a licensed pharmacy located in this state that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians, as defined in Section 4132, where pharmaceutical care services, including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling, are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

(b) Unless otherwise specified in this chapter, a remote dispensing site pharmacy shall comply with all state and federal laws regulating the practice of pharmacy.

Section 4044.6 is added to the Business and Professions Code, to read:

(a) “Supervising pharmacy” means a licensed pharmacy located in this state that is owned and operated by a person or persons where the majority of the beneficial interest in, as well as the management and control, resides with at least one board-licensed pharmacist, as defined in Section 4036, that exclusively oversees the operations of a remote dispensing site pharmacy.

(b) A supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing site pharmacy and its employees pursuant to Section 4131.

Section 4044.7 is added to the Business and Professions Code, to read:

“Telepharmacy” means a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy and provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.

Section 4052.10 is added to the Business and Professions Code, to read:

(a) A pharmacist may dispense a Schedule II controlled substance, as listed in Section 11055 of the Health and Safety Code, as a partial fill if requested by the patient or the prescriber.

(b) If a pharmacist dispenses a partial fill on a prescription pursuant to this section, the pharmacy shall retain the original prescription, with a notation of how much of the prescription has been filled, until the prescription has been fully dispensed. The total quantity dispensed shall not exceed the total quantity prescribed.

(c) Subsequent fills, until the original prescription is completely dispensed, shall occur at the pharmacy where the original prescription was partially filled. The full prescription shall be dispensed not more than 30 days after the date on which the prescription was written. Thirty-one days after the date on which the prescription was written, the prescription shall expire and no more of the drug shall be dispensed without a subsequent prescription.

(d) The pharmacist shall record in the state prescription drug monitoring program only the actual amounts of the drug dispensed.

(e) The pharmacist shall record the date and amount of each partial fill in a readily retrievable form and on the original prescription, and shall include the initials of the pharmacist who dispensed each partial fill.

(f) A pharmacist may charge a professional dispensing fee to cover the actual supply and labor costs associated with dispensing each partial fill associated with the original prescription.

(g) This section shall not be construed to limit the authority of the Department of Managed Health Care, pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(h) This section is not intended to conflict with or supersede any other requirement established for the prescription of a Schedule II controlled substance.

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

(1) "Original prescription" means the prescription presented by the patient to the pharmacy or submitted electronically to the pharmacy.

(2) "Partial fill" means a part of a prescription filled that is of a quantity less than the entire prescription.

(j) This section shall become operative on July 1, 2018.

Section 4053.2 is added to the Business and Professions Code, to read:

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

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

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

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

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

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

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

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

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

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

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

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

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

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

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

(a) Except as provided in ~~Sections 4006, 4240, and 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.

(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 4059.5 of the Business and Professions Code is amended to read:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following

receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other ~~provision of~~ law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this

section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

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, 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 4084.1 is added to the Business and Professions Code, to read:

The board may embargo any nonprescription diabetes test device that a board inspector finds or has probable cause to believe 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. For the purposes of this section, the board shall embargo these products following the same procedures and protections used for adulterated, misbranded, or counterfeit drugs or dangerous devices in Sections 4084, 4085, and 4086.

Section 4100 of the Business and Professions Code is amended to read:

~~(a)~~ -Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, designated

representative, designated representative-3PL, or designated representative-representative-reverse distributor shall notify the executive officer of the board of the change of address or change of name.

~~(b) This section shall become operative on January 1, 2006.~~

Section 4107 of the Business and Professions Code is amended to read:

(a) The board shall not issue more than one site license to a single premises except as follows:

(1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196.

(2) To issue a license to compound sterile drugs to a pharmacy pursuant to Section 4127.1 or 4127.2.

(3) To issue a centralized hospital packaging license pursuant to Section 4128.

(4) To issue licenses to two independently owned clinics that share a clinic office space pursuant to Section 4180.5.

(b) For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

Section 4119 of the Business and Professions Code is amended to read:

(a) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to ~~24~~ 48.

(b) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances ~~Act~~. Act (Division 10 commencing with Section 11000) of the Health and Safety Code).

Section 4119.01 is added to the Business and Professions Code, to read:

(a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars (\$100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars (\$35).

(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars (\$780).

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

Section 4127.15 is added to the Business and Professions Code, to read:

Subject to the requirements of this section, the board may issue a license to a hospital satellite compounding pharmacy. The license fee and annual renewal fee shall be in an amount established by the board in subdivision (u) of Section 4400. The license shall not be transferable.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(1) A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

(2) The services provided shall be directly related to the services or treatment plan administered in the physical plant.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the hospital satellite compounding pharmacy's policies and procedures for sterile compounding.

(2) Reviews the hospital satellite compounding pharmacy's completed self-assessment form as described in Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

(1) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy as defined in subdivision (a) of Section 4029.

(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty.

(3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding.

(4) Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.

(5) Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects shall also be, within 12 hours, reported to the MedWatch program of the federal Food and Drug Administration.

Section 4127.7 of the Business and Professions Code is repealed.

~~A pharmacy shall compound sterile products from one or more nonsterile ingredients in one of the following environments:~~

~~(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.~~

~~(b) An ISO class 5 cleanroom.~~

~~(c) A barrier isolator that provides an ISO class 5 environment for compounding.~~

Article 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Section 4130 is added to the Business and Professions Code, to read:

(a) A telepharmacy system shall be used for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at a remote dispensing site pharmacy.

(b) If all of the requirements of this article and other relevant provisions of this chapter are met, the board shall issue a remote dispensing site pharmacy license for the purpose of increasing

access to dispensing or pharmaceutical care services in the geographic area in which the remote dispensing site pharmacy is to be located.

(c) (1) A remote dispensing site pharmacy shall only be located in a medically underserved area unless otherwise approved by the board. For purposes of this section, a "medically underserved area" means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site.

(2) Notwithstanding paragraph (1), if a pharmacy serving the general public is later established within 10 road miles of a remote dispensing site pharmacy, the remote dispensing site pharmacy may continue to operate.

(d) A remote dispensing site pharmacy shall only be staffed by pharmacists or pharmacy technicians, or both, and shall not employ any unlicensed personnel.

(e) A remote dispensing site pharmacy license shall be issued only to the supervising pharmacy. A supervising pharmacy shall not obtain more than one remote dispensing site pharmacy license.

(f) A remote dispensing site pharmacy shall not be operated by the state and shall not be located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. This section shall not be construed to preclude a pharmacist who is otherwise eligible to operate a remote dispensing site pharmacy pursuant to this section from leasing space in property owned by the state, provided it is not for the purpose of serving individuals otherwise served by pharmacists and pharmacy technicians employed by the state.

(g) A remote dispensing site pharmacy shall not be located or operated for the purpose of displacing state employees.

(h) If a remote dispensing site pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year, it shall cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy.

Section 4131 is added to the Business and Professions Code, to read:

(a) A supervising pharmacy shall provide telepharmacy services for only one remote dispensing site pharmacy.

(b) A supervising pharmacy shall not be located greater than 150 road miles from a remote dispensing site pharmacy, unless otherwise approved by the board.

(c) A supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.

(d) Unless staffed by a pharmacist, a remote dispensing site pharmacy shall be staffed by at least one registered pharmacy technician meeting the qualifications of Section 4132. A technician shall remain under the direct supervision and control of a pharmacist at the

supervising pharmacy at all times that the remote dispensing site pharmacy is operational. For the purposes of this article, direct supervision and control does not require the pharmacist to be physically present at the remote dispensing site pharmacy, but the pharmacist shall use a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy.

(e) Notwithstanding any other law, a pharmacist may serve as the pharmacist-in-charge for a pharmacy in addition to serving as pharmacist-in-charge of a supervising pharmacy. The designated pharmacist-in-charge of the supervising pharmacy shall also serve as the designated pharmacist-in-charge at the remote dispensing site pharmacy.

(f) Notwithstanding any other law, the pharmacist-in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy shall be responsible for ensuring that both the supervising pharmacy and remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.

Section 4132 is added to the Business and Professions Code, to read.

(a) In addition to the requirements of Section 4202, a pharmacy technician working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians working at remote dispensing sites.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(7) Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

Section 4133 is added to the Business and Professions Code, to read:

(a) A telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients.

(b) A telepharmacy system shall facilitate adequate pharmacist supervision and allow the appropriate exchange of visual, verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs.

(c) Patient counseling shall be provided using audio-visual communication prior to all prescriptions being dispensed from a remote dispensing site pharmacy.

(d) A telepharmacy system shall be able to do all of the following:

(1) Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.

(2) Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription.

(3) Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed.

(4) Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing.

(5) Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery.

(e) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191).

(f) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription.

Section 4134 is added to the Business and Professions Code, to read:

(a) A pharmacist from the supervising pharmacy shall complete a monthly in-person, self-inspection of each remote dispensing site pharmacy using a form designated by the board and shall retain all inspection reports.

(b) A perpetual inventory shall be kept for all controlled substances stored at a remote dispensing site pharmacy.

(c) All controlled substances at a remote dispensing site pharmacy shall be stored in a secure cabinet or safe that is locked.

(d) A pharmacist from the supervising pharmacy shall perform inventory and inventory reconciliation functions at a remote dispensing site pharmacy to detect and prevent the loss of any controlled substance.

(e) The pharmacist-in-charge of a remote dispensing site pharmacy shall review all inventory and inventory reconciliation reports taken and shall establish and maintain secure methods to prevent losses of any controlled substance. The board shall develop written policies and procedures for performing the inventory reconciliation reports required by this section.

(f) A pharmacist from the supervising pharmacy shall compile an inventory reconciliation report of all Schedule II controlled substances at a remote dispensing site pharmacy at least once every three months. This compilation shall require all of the following:

(1) A physical count, not an estimate, of all quantities of Schedule II controlled substances at the remote dispensing site pharmacy. The biennial inventory of controlled substances as required under federal law may serve as one of the mandated inventories under this section in the year that the federal biennial inventory is performed, provided that the biennial inventory was taken no more than three months from the last inventory required by this section.

(2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last inventory reconciliation report.

(3) A comparison of paragraphs (1) and (2) in order to determine if there are any variances.

(4) All records used to compile each inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

(g) A remote dispensing site pharmacy shall report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss. If the remote dispensing site pharmacy is unable to identify the cause of the loss, the remote dispensing site pharmacy shall undertake further

investigation to identify the cause of the loss and security improvements necessary to prevent any additional losses of controlled substances. The pharmacist-in-charge shall be responsible for submitting the report to the board.

(h) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(i) The inventory reconciliation report shall be dated and signed by the individual or individuals performing the inventory and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy. A countersignature shall not be required if the pharmacist-in-charge personally completed the inventory reconciliation report. The inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

Section 4135 is added to the Business and Professions Code, to read

(a) While closed, a remote dispensing site pharmacy shall utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(b) Unless a pharmacist is present at the remote dispensing site pharmacy, a remote dispensing site pharmacy shall not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system shall allow for tracking of entries into the remote dispensing site pharmacy and the pharmacist-in-charge shall periodically review the record of entries. Pharmacy services shall not be provided at a remote dispensing site pharmacy if the telepharmacy system is unavailable.

(c) The remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 120 days.

Section 4160 of the Business and Professions Code is amended to read:

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

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

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

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

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

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

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

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

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

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge. *A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.*

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's

specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another ~~designated representative or pharmacist~~ authorized licensee to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

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

Section 4160.5 is added to the Business and Professions Code, to read:

Within 30 days of the effective date of the act adding this section, a manufacturer of a nonprescription diabetes test device shall make the names of its authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. Within 30 days of receiving that information from a manufacturer of a nonprescription diabetes test device, the board shall post the names of authorized distributors of nonprescription diabetes test devices on the board's Internet Web site. A manufacturer of a nonprescription diabetes test device shall, within 30 days of making changes to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. Within 30 days of receiving notice of any change from a manufacturer of a nonprescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.

Section 4169.1 is added to the Business and Professions Code, to read:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Section 4170 of the Business and Professions Code is amended to read:

(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

- (1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
- (2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
- (3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
- (4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.
- (5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).
- (6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.
- (7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the California Board of Podiatric Medicine, ~~the~~ Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the California Board of ~~Osteopathic Examiners of this state~~. Podiatric Medicine.

Section 4175 of the Business and Professions Code is amended to read:

(a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Veterinary Medical Board, the Dental Board of California, the State Board of Optometry, the California Board of Podiatric Medicine, ~~the~~ Osteopathic Medical Board of California, the Board of Registered Nursing, the Bureau of Naturopathic Medicine, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, naturopathic doctors, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the California Board of Podiatric Medicine, ~~the~~ Osteopathic Medical Board of California, the Bureau of Naturopathic Medicine, the Board of Registered Nursing, the Veterinary Medical Board, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

Section 4180.5 is added to the Business and Professions Code, to read:

(a) The board may issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space, provided that the clinics comply with the following:

(1) Each clinic maintains a separate clinic license with the board with its own professional directors, administrators, owners, and officers.

(2) Each clinic maintains physically separate and locked drug stocks.

(3) Each clinic separately maintains all records required by this article, including acquisition and disposition records.

(4) Dangerous drugs and dangerous devices shall not be loaned between the two licensed clinics.

(b) Dangerous drugs and dangerous device losses at the shared clinic office shall be reported to the board as required by law. Each clinic may be jointly and severally responsible for the drug losses.

(c) The applicants shall also provide the board with a copy of the co-location agreement and a one-time application fee of seven hundred fifty dollars (\$750) for the licenses.

(d) Any change in ownership in either clinic shall require a new application under this section and fees as required by subdivision (a) of Section 4400 and subdivision (c) of this section.

(e) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to this section until the board is provided with documentation from the Director of the Department of Health Care Services that any Medi-Cal financing issues, including the ability to claim associated federal financial participation or 340(b) program participation, have been sufficiently addressed to the director's satisfaction. The Department of Health Care Services may seek any federal approvals it deems necessary to implement this section.

(f) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to the section until the board is provided with documentation from the Director of the Department of Public Health that any licensing and regulatory issues have been sufficiently addressed to the director's satisfaction.

(g) This section shall become inoperative on January 1, 2021, and as of that date is repealed.

Section 4200.4 of the Business and Professions Code is amended to read:

An applicant who fails ~~the national examination~~ either the North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists may not retake ~~the that~~ the that examination for at least ~~90 days or for a period established by regulations adopted by the board~~ 45 days. The board may, in consultation with the Office of Professional Examination Services of the department, adopt a regulation establishing a different waiting period to retake the examination.

Section 4202.5 is added to the Business and Professions Code, to read:

(a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars (\$140) for a two-year license. The biennial renewal shall be one hundred forty dollars (\$140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars (\$65).

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, 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 Medi-Cal 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 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 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 4316 of the Business and Professions Code is amended to read:

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

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

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order.

Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the ~~pharmacy~~ facility pursuant to Section 1094.5 of the Code of Civil Procedure.

Section 4331 of the Business and Professions Code is amended to read:

(a) A person ~~who is not a pharmacist, a designated representative in charge, or a designated representative and~~ not authorized under this chapter who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) A person who is not a responsible manager or a designated representative-3PL who takes charge of a third-party logistics provider or coordinates the warehousing or distribution of dangerous drugs or dangerous devices within a third-party logistics provider, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person licensed as a veterinary food-animal drug retailer that fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) A person licensed as a wholesaler that fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) A person licensed as a third-party logistics provider that fails to place in charge of a licensed place of business of the third-party logistics provider a responsible manager, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a facility manager, or as otherwise provided in this chapter, is guilty of a misdemeanor.

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, ~~or 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~~ representative, designated representative-3PL, or designated ~~representative-3PL~~ 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.

Health and Safety Code Section Changes

Section 11054 of the Health and Safety Code is amended to read:

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

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their 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:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmethadol (except levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Diampromide.
- (14) Diethylthiambutene.
- (15) Difenoxin.
- (16) Dimenoxadol.
- (17) Dimepheptanol.
- (18) Dimethylthiambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxidine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacymorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpipanone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.

(39) Proheptazine.

(40) Properidine.

(41) Propiram.

(42) Racemoramide.

(43) Tilidine.

(44) Trimeperidine.

(45) Any substance which contains any quantity of acetylfentanyl (N-[1-phenethyl-4-piperidinyl] acetanilide) or a derivative thereof.

(46) Any substance which contains any quantity of the thiophene analog of acetylfentanyl (N-[1-[2-(2-thienyl)ethyl]-4-piperidinyl] acetanilide) or a derivative thereof.

(47) 1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).

(48) 1-(2-Phenethyl)-4-Phenyl-4-Acetyloxypiperidine (PEPAP).

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, 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) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Drotebanol.

(10) Etorphine (except hydrochloride salt).

(11) Heroin.

(12) Hydromorphanol.

(13) Methyldesorphine.

(14) Methyldihydromorphine.

(15) Morphine methylbromide.

(16) Morphine methylsulfonate.

(17) Morphine-N-Oxide.

(18) Myrophine.

(19) Nicocodeine.

(20) Nicomorphine.

(21) Normorphine.

(22) Pholcodine.

(23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 4-bromo-2,5-dimethoxy-amphetamine—Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA.

(2) 2,5-dimethoxyamphetamine—Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.

(3) 4-methoxyamphetamine—Some trade or other names: 4-methoxy-alpha-methylphenethylamine, paramethoxyamphetamine, PMA.

(4) 5-methoxy-3,4-methylenedioxy-amphetamine.

(5) 4-methyl-2,5-dimethoxy-amphetamine—Some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP."

(6) 3,4-methylenedioxy amphetamine.

(7) 3,4,5-trimethoxy amphetamine.

(8) Bufotenine—Some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5 indolol; N,N-dimethylserolonin, 5-hydroxy-N,N-dimethyltryptamine; mappine.

(9) Diethyltryptamine—Some trade or other names: N,N-Diethyltryptamine; DET.

(10) Dimethyltryptamine—Some trade or other names: DMT.

(11) Ibogaine—Some trade or other names: 7-Ethyl-6,6beta, 7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1',2':1,2] azepero [5,4-b] indole; Tabernantheiboga.

(12) Lysergic acid diethylamide.

(13) ~~Marijuana~~—Cannabis.

(14) Mescaline.

(15) Peyote—Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts (interprets 21 U.S.C. Sec. 812(c), Schedule 1(c)(12)).

(16) N-ethyl-3-piperidyl benzilate.

(17) N-methyl-3-piperidyl benzilate.

(18) Psilocybin.

(19) Psilocyn.

(20) Tetrahydrocannabinols. Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following: delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; delta 3,4 cis or trans tetrahydrocannabinol, and its optical isomers.

~~(Since Because nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).~~ covered.

(21) Ethylamine analog of phencyclidine—Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE.

(22) Pyrrolidine analog of phencyclidine—Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCP, PHP.

(23) Thiophene analog of phencyclidine—Some trade or other names: 1-[1-(2 thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP.

(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) Mecloqualone.

(2) Methaqualone.

(3) Gamma hydroxybutyric acid (also known by other names such as GHB; gamma hydroxy butyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate), including its immediate precursors, isomers, esters, ethers, salts, and salts of isomers, esters,

and ethers, including, but not limited to, gammabutyrolactone, for which an application has not been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(f) 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, including its isomers:

(1) Cocaine base.

(2) Fenethylamine, including its salts.

(3) N-Ethylamphetamine, including its salts.

Section 11165.1 of the Health and Safety Code, is amended to read:

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the ~~Department of Justice~~ department to obtain approval to electronically access information ~~online~~ regarding the controlled substance history of a patient that is ~~stored on the Internet and maintained within the Department of Justice, and, upon~~ maintained by the department. Upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the ~~Department of Justice~~ department to obtain approval to electronically access information ~~online~~ regarding the controlled substance history of a patient that is ~~stored on the Internet and maintained within the Department of Justice, and, upon~~ maintained by the department. Upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application ~~for a subscriber~~ to access information contained in the CURES database.

(ii) ~~Failure~~ Failing to maintain effective controls for access to the patient activity report.

(iii) ~~Suspended~~ Having his or revoked her federal DEA ~~registration~~ registration suspended or revoked.

(iv) ~~Any subscriber who is arrested for a violation of~~ Violating a law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

~~(v) Any subscriber accessing~~ Accessing information for ~~any a reason~~ other reason than caring for than to diagnose or treat his or her patients, patients, or to document compliance with the law.

~~(C) Any An~~ authorized subscriber shall notify the ~~Department of Justice~~ department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from

the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) ~~Any A~~ request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the ~~Department of Justice.~~ department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the ~~Department of Justice~~ department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the ~~Department of Justice~~ department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a ~~prescriber~~ practitioner or pharmacist pursuant to this section shall include prescriptions for

controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

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

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(5) "User-initiated basis" means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

Section 11220 of the Health and Safety Code is amended to read:

At the end of 30 days from the first treatment, the prescribing or furnishing of controlled substances, except ~~methadone or LAAM,~~ medications approved by the federal Food and Drug Administration for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders, shall be discontinued.