2026 LAWBOOK FOR PHARMACY

The Pharmacy Law
(Business and Professions Code 4000 *et seq*.)

Excerpts from the Business and Professions Code
Board of Pharmacy Regulations
(California Code of Regulations,
Title 16, Section 1700 *et seq*.)

Excerpts from
The California Uniform Controlled Substances Act
(Health and Safety Code 11000 *et seq*.)

Excerpts from
The Confidentiality of Medical Information Act
(Civil Code 56 *et seq*.)

Excerpts from the Public Resources Code

CALIFORNIA STATE
BOARD OF PHARMACY

BE AWARE AND TAKE CARE: Talk to your pharmacist!

Rev 2/2026

The Pharmacy Lawbook is a compilation of California laws and regulations governing the practice of pharmacy in California, but is not an official edition of those laws and regulations. While we try to ensure that the material in the Pharmacy Lawbook is accurate and up-to-date, those relying on it for legal research should verify their results against the most current official edition of California statutes and regulations, available at http://leginfo.legislature.ca.gov and https://govt.westlaw.com/calregs

Updated 2/2026 to correct BPC section 4064.5(e)

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BUSINESS & PROFESSIONS CODE
CHAPTER 9, DIVISION 2

Article 1. Administration

4000. Chapter Title

This chapter constitutes, and may be cited as, the Pharmacy Law.

4001. Board of Pharmacy; Appointment; Terms

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

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

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, a compounding pharmacy specializing in human drug preparations, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a “chain

community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.
(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of their successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.
(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.
(f) This section shall remain in effect only until January 1, 2030, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

4001.1. Protection of the Public is Board's Highest Priority

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

4001.5 Pharmacy Technician Advisory Committee

(a) The board shall establish and appoint a Pharmacy Technician Advisory Committee to advise and make recommendations to the board on matters relating to pharmacy technicians.
(b) The committee shall serve only in an advisory capacity to the board and the objectives, duties, and actions of the committee shall not be a substitute for, nor conflict with, any of the powers, duties, and responsibilities of the board.
(c) The committee shall consist of the following:
(1) Four licensed pharmacy technicians representing a range of practice settings to provide a diversity of perspectives.

(2) Two licensed pharmacists, of whom one shall be a member of the board and shall be appointed by the board president.
(3) One member of the public.

4002. Officers
(a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.
(b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Members of the board may meet by teleconference pursuant to Section 11123 of the Government Code. Seven members of the board constitute a quorum.

4003. Executive Officer; Records; Revenue
(a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in them by this chapter. The executive officer shall not be a member of the board.
(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of their duties.
(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.
(d) The executive officer shall give receipts for all money received by them and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of them by the board.
(e) This section shall remain in effect only until January 1, 2030, and as of that date is repealed.

4004. Teaching by Board Members

No member of the board shall teach pharmacy in any of its branches, unless he or she teaches as either one of the following:

(a) A teacher in a public capacity and in a college of pharmacy.

(b) A teacher of an approved continuing education class as, or under the control of, an accredited provider of continuing education.

4005. Adoption of Rules and Regulations

(a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4006. Regulations Restricting Furnishing of Particular Drug

The board may adopt regulations consistent with this chapter and Section 111485 of the Health and Safety Code or regulations adopted thereunder, limiting or restricting the furnishing of a particular drug upon a finding that the otherwise unrestricted retail sale of the drug pursuant to Section 4057 is dangerous to the public health or safety.

4007. Limitations of Rules

(a) Nothing in Section 4005 shall be construed as authorizing the board to adopt rules of professional conduct relating to price fixing or advertising of commodities.

(b) Nothing in Section 4005 shall be construed as authorizing the board to adopt any rule or regulation that would require that a pharmacist personally perform any function for which the education, experience, training, and specialized knowledge of a pharmacist are not reasonably required. However, rules and regulations may require that the function be performed only under the effective supervision of a pharmacist who shall have the overall responsibility for supervising all activities that take place in the pharmacy.

4008. Inspectors; Authority as Public Officers

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

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

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as

a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in the officer's presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

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

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

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

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

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

(g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery

system to inspect that automated drug delivery system or proposed location pursuant to Article 25 (commencing with Section 4427).

4009. Board Rules; Exemption From Coverage Under Industrial Welfare Commission Rules

The board may not adopt or amend any rule or regulation that thereby would conflict with Section 1186 of the Labor Code.

4010. Immunity of Officers

All authorized officers of the law, while investigating violations of this chapter in performance of their official duties, and any person working under their immediate direction, supervision, or instruction are immune from prosecution under this chapter.

4011. Administration and Enforcement of Uniform Controlled Substances Act

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

4012. Board to Provide Copy of Laws or Regulations

The board shall upon request furnish any person with a copy of the laws or regulations relating to dangerous drugs, the furnishing or possession of which is restricted by this article or by further rules of the board.

4013. Board licensed Facilities Required to Join Board's E-Mail Notification List

(a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.
(b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.
(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email

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

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

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

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

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

4014. Board of Pharmacy Exclusive Authority

(a) The board shall have exclusive authority to interpret and enforce the provisions of this chapter regarding the practice of pharmacy and the licensing of pharmacists and pharmacies.

(b) Any violation of this chapter by a licensee of the board shall be determined exclusively by the board.

(c) The board shall have the sole authority to conduct investigations, hold hearings, and impose disciplinary actions for violations of this chapter by licensees of the board.
(d) Nothing in this section shall be construed to prohibit the board from evaluating or acting regarding unlicensed activity.

Article 2. Definitions

4015. Definitions to Govern Construction
For purposes of this chapter, the definitions of the terms in this article shall govern the construction of this chapter, unless otherwise indicated.

4016. Administer
"Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

4016.5. Advanced Pharmacist Practitioner
“Advanced pharmacist practitioner” means a licensed pharmacist who has been recognized as an advanced pharmacist practitioner by the board, pursuant to Section 4210. A board-recognized advanced pharmacist practitioner is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

4017. Authorized Officers of the Law
"Authorized officers of the law" means inspectors of the California State Board of Pharmacy, inspectors of the Food and Drug Branch of the State Department of Public Health, and investigators of the department's Division of Investigation or peace officers engaged in official investigations.

4017.3. Automated Drug Delivery System; Automated Unit Dose System; Automated Patient Dispensing System

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

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

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

4018. Board

"Board" means the California State Board of Pharmacy.

4019. Chart Order

An "order," entered on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by law to prescribe drugs, shall be authorization for the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted under Section 4056, and shall be considered to be a prescription if the medication is to be furnished directly to the patient by the hospital pharmacy or another pharmacy furnishing prescribed drugs for hospital patients; provided that the chart or medical record of the patient contains all of the information required by Sections 4040 and 4070 and the order is signed by the practitioner authorized by law to prescribe drugs, if he or she is present when the drugs are given. If he or she is not present when the drugs are given, the order shall be signed either by the attending physician responsible for the patient's care at the time the drugs are given to the patient or by the practitioner who

ordered the drugs for the patient on the practitioner's next visit to the hospital.

4021. Controlled Substance

"Controlled substance" means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

4021.5. Correctional Pharmacy

(a) “Correctional pharmacy” means a pharmacy, licensed by the board, for the purpose of providing drugs and pharmaceutical care to inmates of the Department of Corrections and Rehabilitation.
(b) As part of its pharmaceutical care,
a correctional pharmacy may dispense or administer medication pursuant to a chart order, as defined in Section 4019, or other valid prescription consistent with this chapter.

4022. Dangerous Drug – Dangerous Device Defined

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

4022.5. Designated Representative; Designated Representative-in-Charge

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

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

4022.6. Designated Representative-Reverse Distributor

"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.

4022.7. Designated Representative-3PL; Responsible Manager

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

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

4023. Device

"Device" means any instrument, apparatus, machine, implant, in vitro reagent, or contrivance, including its components, parts, products, or the byproducts of a device, and accessories that are used or intended for either of the following:

(a) Use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or any other animal.

(b) To affect the structure or any function of the body of a human or any other animal.

For purposes of this chapter, "device" does not include contact lenses, or any prosthetic or orthopedic device that does not require a prescription.

4023.5. Direct Supervision and Control

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

4024. Dispense

(a) Except as provided in subdivision (b), "dispense" means the furnishing of drugs or devices upon a prescription from a physician, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or upon an order to furnish drugs or transmit a prescription from a certified nurse-midwife, nurse practitioner practicing pursuant to Section 2836.1, physician assistant, naturopathic doctor pursuant to Section 3640.5, or pharmacist acting within the scope of their practice.

(b) "Dispense" also means and refers to the furnishing of drugs or devices directly to a patient by a physician, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, dentist, optometrist, podiatrist, or veterinarian, or by a certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant acting within the scope of their practice.

4025. Drug

"Drug" means any of the following:

(a) Articles recognized in the official United States Pharmacopoeia, official National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement of any of them.

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(c) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

4025.1. Non-Prescription Drug

"Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

4025.2. Nonprescription Diabetes Test Device

“Nonprescription diabetes test device” means a glucose meter or test strip for use in the treatment of prediabetic or diabetic individuals that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

4026. Furnish

"Furnish" means to supply by any means, by sale or otherwise.

4026.5. Good Standing

"Good standing" means a license issued by the board that is unrestricted by disciplinary action taken pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

4027. Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

(a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in Section 4052.1, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in Section 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Public Health pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

4028. Licensed Hospital

"Licensed hospital" means an institution, place, building, or agency that maintains and operates organized facilities for one or more persons for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay, and includes any institution classified under regulations issued by the State Department of Public Health as a general or specialized hospital, as a maternity hospital, or as a tuberculosis hospital, but does not include a sanitarium, rest home, a nursing or convalescent home, a maternity home, or an institution for treating alcoholics.

4029. Hospital Pharmacy

(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 may include a pharmacy that is located in any physical plant that is regulated under 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.

4030. Intern Pharmacist

"Intern pharmacist" means a person issued a license pursuant to Section 4208.

4031. Laboratory

"Laboratory" means a research, teaching, or testing laboratory not engaged in the dispensing or furnishing of drugs or devices but using dangerous drugs or dangerous devices for scientific or teaching purposes. Every laboratory shall maintain an established place of business and keep purchase records. Every laboratory shall be subject to the jurisdiction of the board.

4032. License

"License" means and includes any license, permit, registration, certificate, or exemption issued by the board and includes the process of applying for and renewing the same.

4033. Manufacturer

(a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug

previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

4034. Outsourcing Facility

"Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

(c) Is doing business within or into California.

(d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).

4034.5. Emergency Medical Service Automated Drug Delivery System

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.

4035. Person

"Person" includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision.

4036. Pharmacist

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy.

4036.5. Pharmacist-in-Charge

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacist is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Public Health where floor supplies,

ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

4038. Pharmacy Technician

(a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of their pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education or an accredited employer-based pharmacy technician training program.

4039. Physician; Other Practitioners Defined

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

4040. Prescription; Content Requirements

(a) “Prescription” means an oral, written, or electronic transmission order that is both of the following:

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

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

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

(C) The date of issue.

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

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

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052, 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052, 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

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

Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.
(c) “Electronic transmission prescription” includes both image and data prescriptions. “Electronic image transmission prescription” means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. “Electronic data transmission prescription” means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.
(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

4040.5. Reverse Distributor

“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 or dangerous devices.

4040.6. Self-Assessment Requirement

“Self-assessment process” means the process of self-evaluation of a facility’s compliance with state and federal laws as a means to promote compliance through self-examination and education. The self-assessment process shall be performed on a form approved by the board in consultation with stakeholders and posted on its internet website.

4041. Veterinary Food-Animal Drug Retailer

"Veterinary food-animal drug retailer" is an area, place, or premises, other than a pharmacy, that holds a valid license from the Board of Pharmacy of the State of California as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed veterinarian. "Veterinary food-animal retailer" includes, but is not limited to, any area, place, or premises described in a permit issued by the board wherein veterinary food-animal drugs, as

defined in Section 4042, are stored, possessed, or repackaged, and from which veterinary drugs are furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

4042. Veterinary Food-Animal Drugs

"Veterinary food-animal drugs" as used in this chapter shall include the following:

(a) Any drug to be used in food-producing animals bearing the legend, "Caution, federal law restricts this drug to use by or on the order of a licensed veterinarian" or words of similar import.

(b) Any other drug as defined in Section 14206 of the Food and Agricultural Code that is used in a manner that would require a veterinary prescription.

4043. Wholesaler

“Wholesaler” means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

4044. Repackager

"Repackager" means a person or entity that is registered with the federal Food and Drug Administration as a repackager and operates an establishment that packages finished drugs from bulk or that repackages dangerous drugs into different containers, excluding shipping containers.

4044.3. Remote Dispensing Site Pharmacy

(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.

4044.5. Reverse Third-Party Logistics Provider

"Reverse third-party logistics provider" means an entity that processes or manages the disposition of an outdated or nonsaleable dangerous drug or dangerous device on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device nor have the responsibility to direct its sale or disposition. Unless otherwise specified in this chapter, every provision of this chapter that applies to a third-party logistics provider shall also apply to a reverse third-party logistics provider.

4044.6. Supervising Pharmacy

(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.

4044.7. Telepharmacy

"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.

4045. Third-Party Logistics Provider

"Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services for a dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device, nor have responsibility to direct its sale or disposition.

4046. Surplus Medication Collection and Distribution Intermediary

"Surplus medication collection and distribution intermediary" means a firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision that performs the functions specified in Section 4169.5 for the purpose of a program established pursuant to Division 116 (commencing with section 150200) of the Health and Safety Code.

Article 3. Scope of Practice and Exemptions

4050. Legislative Declaration

(a) For the purposes of this section, "state agency" includes every state office, officer, department, division, bureau, board, authority, and commission.

(b) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(c) Pharmacist practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of patient-care activities to optimize appropriate drug use, drug-related therapy, disease management and prevention, and communication for clinical and

consultative purposes. Pharmacist practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(d) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

(e) No state agency other than the board may define or interpret this chapter and its regulations for those licensed pursuant to this chapter or develop standardized procedures or protocols pursuant to this chapter, unless so authorized by this chapter, or specifically required under state or federal law.

4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

(a) For the purposes of this section, "accepted standard of care" means the degree of care a prudent and reasonable pharmacist licensed pursuant to this chapter, with similar education, training, experience, resources, and setting, would exercise in a similar situation.

(b) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(c) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, 4052.3, or 4052.6, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) The pharmacist provides the service or activity consistent with the accepted standard of care.

4052. Furnishing to Prescriber; Permitted Procedures by Pharmacist

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

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

(2) Transmit a valid prescription to another pharmacist.

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

(4) Perform procedures or functions as authorized by Sections 4052.1 and 4052.2.

(5) Furnish epinephrine.

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

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

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention, and furnish over-the-counter medications if requested.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to patients and health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10)(A) Furnish FDA-approved or authorized medications as part of preventative health care services that do not require a diagnosis, including any of the following:

(i) Emergency contraception. A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision. .

(ii) Contraception.

(iii) Smoking cessation.

(iv) Travel medication.

(v) Anti-viral or anti-infective medications.

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

(C) Nothing in this section shall be construed as establishing an obligation on a pharmacist to report an over-the-counter medication sold to a patient that was not captured as a prescription.

(11) Order and interpret tests.

(12) Initiate, adjust, or discontinue drug therapy for a patient under either of the following

(A) A collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

(B) An order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the entity providing health care services, unless a patient's treating prescriber otherwise prohibits the action.

(13) Furnish medication used to reverse opioid overdose and medication used to treat substance use disorder to the extent authorized by federal law.

(14) Complete missing information on a prescription for a noncontrolled medication if there is evidence to support the change.

(15) Initiate and administer immunizations for persons three years of age and older pursuant to this article.

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

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

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) if the pharmacist has made a professional determination that any of the following apply:

(1) The pharmacist lacks sufficient education, training, or expertise, or access to sufficient patient medical information, to perform the service or function properly or safely.

(2) Performing or providing the service or function would place a patient at risk.

(3) Pharmacist staffing at the pharmacy is insufficient to facilitate comprehensive patient care.

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

(f) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide authorized services without payment for the services, including payment directly by the patient, payment through a third-party payer, or payment of any required copayment by the patient.

4052.04 Pharmacists may furnish COVID-19 oral therapeutics

(a) In addition to the authority provided in Section 4052, a pharmacist may furnish COVID-19 oral therapeutics following a positive test for SARS-CoV-2, the virus that causes COVID-19.

(b) Prior to furnishing COVID-19 oral therapeutics pursuant to subdivision (a), a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by the federal Food and Drug Administration in providing these patient care services.

(c) A pharmacist who furnishes COVID-19 oral therapeutics shall notify the patient's primary care provider, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.

(d) A pharmacist shall document, to the extent possible, the kind and amounts of COVID-19 oral therapeutics furnished pursuant to subdivision (a), as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. The records shall be maintained for three years and shall be available for inspection by all properly authorized personnel of the board.

(e) For purposes of this section, "COVID-19 oral therapeutics" means drugs that are approved or authorized by the United States Food and Drug Administration for the treatment of COVID-19 and administered orally.

4052.05. Immunization Initiation and Administration

A pharmacist may independently initiate and administer an immunization that, on January 1, 2025, had in effect a recommendation from the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention, regardless of whether the immunization is recommended for routine use, or as modified or supplemented by the State Department of Public Health pursuant to Section

120164 of the Health and Safety Code, to individuals three years of age or older.

4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

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

(2) Ordering drug therapy-related laboratory tests.

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

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

4052.2. Permitted Pharmacist Procedures in Health Care Facility; Home Health Agency or Clinic with Physician Oversight

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional center, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed

correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

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

(2) Ordering drug therapy-related laboratory tests.

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

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

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

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

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

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

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

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

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

(1) Successfully completed clinical residency training.

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

4052.4. Conditions Permitting Pharmacists to Perform Skin Puncture and CLIA-Waived Tests

(a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, “routine patient assessment procedures” means: (a) procedures that a patient could, with or without a prescription, perform for themselves, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:

(1) The test meets the criteria in subparagraph (A) or (B) and does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.

(A) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:

(i) SARS-CoV-2 or other respiratory illness, condition or disease.

(ii) Mononucleosis.

(iii) Sexually transmitted infection.

(iv) Strep throat.

(v) Anemia.

(vi) Cardiovascular health.

(vii) Conjunctivitis.

(viii) Urinary tract infection.

(ix) Liver and kidney function or infection.

(x) Thyroid function.

(xi) Substance use disorder.

(xii) Diabetes.

(B) Other tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration and approved by the board by regulation, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health.

(2) The pharmacist completes the testing in a pharmacy laboratory that is appropriately licensed in California as a laboratory pursuant to Section 1265, unless otherwise authorized in law.

(3) The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures maintained pursuant to subdivision (b) of Section 4119.10, and that allows

the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested, as applicable.

4052.5. Pharmacist May Select Different Form of Medication with Same Active Chemical Ingredients

(a) In addition to the authority allowed under Section 4073, a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute" or words of similar meaning.

Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be

indicated on the prescription label, unless the prescriber orders otherwise.

(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.

4052.6. Advanced Pharmacist Practitioner; Permitted Procedures

(a) A pharmacist recognized by the board as an advanced pharmacist practitioner may do all of the following:

(1) Perform patient assessments.

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

(3) Refer patients to other health care providers.

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

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

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

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

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

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including

promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

4052.10. Partial Fills of Schedule II Controlled Substance

(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.

4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer

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

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

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

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

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

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

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

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

4053.1. Designated Representative 3-PL to Supervise Third-Party Logistics Provider

(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of

dangerous drugs and dangerous devices in the third-party logistics provider's place of business.

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

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

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

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

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

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

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

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

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

(iii) Knowledge and understanding of quality control systems.

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

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

(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of

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

4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements

(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.

4054. Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices

Section 4051 shall not apply to a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.

4055. Sale of Devices to Licensed Clinics, etc.

Nothing in this chapter, nor any other law, shall prohibit the sale of devices to clinics that have been issued a clinic license pursuant to Article 13 (commencing with Section 4180) of this chapter, or to skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of, or to home health agencies licensed pursuant to Chapter 8 (commencing with Section 1725) of, or to hospices licensed pursuant to Chapter 8.5 (commencing with Section

1745) of, Division 2 of, the Health and Safety Code, as long as the devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

4056. Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less

(a) Notwithstanding any provision of this chapter, a licensed hospital that contains 100 beds or fewer, and that does not employ a full-time pharmacist, may purchase drugs at wholesale for administration, under the direction of a physician, or for dispensation by a physician, to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or, under the conditions described in subdivision (f), to persons registered as outpatients in a rural hospital as defined in Section 124840 of the Health and Safety Code. The hospital shall keep records of the kind and amounts of drugs so purchased and administered or dispensed, and the records shall be available for inspection by all properly authorized personnel of the board.

(b) No hospital shall be entitled to the benefits of subdivision (a) until it has obtained a license from the board. Each license shall be issued to a specific hospital and for a specific location.

(c) Each application for a license under this section shall be made on a form furnished by the board. Upon the filing of the application and payment of the fee prescribed in subdivision (a) of Section 4400, the executive officer of the board shall issue a license authorizing the hospital to which it is issued to purchase drugs at wholesale pursuant to subdivision (a). The license shall be renewed annually on or before November 1 of each year upon payment of the renewal fee prescribed in subdivision (b) of Section 4400 and shall not be transferable.

(d) The form of application for a license under this section shall contain the name and address of the applicant, the number of beds, whether the applicant is a licensed hospital, whether it does or does not employ a full-time pharmacist, the name of its chief medical officer, and the name of its administrator.

(e) The board may deny, revoke, or suspend a license issued under this section in the manner and for the grounds specified in Article 19 (commencing with Section 4300).

(f) A physician himself or herself may dispense drugs to outpatients directly pursuant to subdivision (a) only if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius from the hospital pharmaceutical services by means of the method of transportation the patient states that he or she intends to use. The quantity of drugs dispensed to any outpatient pursuant to this subdivision shall be limited to that amount necessary to maintain uninterrupted therapy during the period when pharmaceutical services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply. The physician shall ensure that the label on the drug contains all the information required by Section 4076.

(g) A rural hospital, as defined in Section 124840 of the Health and Safety Code, shall obtain information regarding the hours of operation of each pharmacy located within the 30 minute or 30-mile radius of the hospital. The hospital shall update this information annually, and shall make this information available to its medical staff.

(h) A licensed hospital that contains 100 beds or fewer, does not employ a full-time pharmacist, and purchases drugs at wholesale for administration or dispensation pursuant to subdivision (a), shall retain the services of a pharmacist consultant to monitor and review the pharmaceutical services provided by the hospital to inpatients of the hospital, and the dispensing of drugs by physicians to outpatients pursuant to subdivision (f).

(i) This section shall not be construed to eliminate the requirements of Section 11164 or 11167 of the Health and Safety Code.

4057. Exceptions to Application of this Chapter

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

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

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

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

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

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

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

(2) Hypodermic needles and syringes.

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

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

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

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

4058. Display of Original License

Every person holding a license issued under this chapter to operate a premises shall display the original license and current renewal license upon the licensed premises in a place where it may be clearly read by the public.

4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Public Health. The physician prescribing the dialysis products shall submit proof satisfactory to the

manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Board of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

4059.5. Who May Order Dangerous Drugs or Devices: Exceptions; Compliance With Laws of All Involved Jurisdictions

(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, 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 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.

4060. Controlled Substance: Prescription Required; Exceptions

A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or

naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner practicing pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer.

This section does not authorize a certified nurse-midwife, a nurse practitioner practicing pursuant to Section 2836.1, a physician assistant, or a naturopathic doctor, to order their own stock of dangerous drugs and devices.

4061. Distribution of a Drug as Sample; Written Request Required

(a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, veterinarian, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or naturopathic doctor pursuant to Section 3640.7. However, 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 a protocol described in Section 3502.1, or a naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include

specific approval by a physician. A review process, consistent with the requirements of Section 2725, 3502.1, or 3640.5, of the complimentary samples requested and received by a nurse practitioner practicing pursuant to Section 2836.1, certified nurse-midwife, physician assistant, or naturopathic doctor, shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor.

4062. Furnishing Dangerous Drugs during Emergency; Mobile Pharmacy

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

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or

the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

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

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

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

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

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

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

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

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

(e) (1) A pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, may be relocated. The relocation shall not be considered a transfer of ownership or location under Section 4110, if no changes are made to the management and control, or ownership, of the pharmacy and all applicable laws and regulations are followed. Notification of the

relocation shall be provided to the board immediately upon identification of the new location.

(2) For purposes of this section, “severely damaged” means damage that renders the premises unsafe or unfit for entry or occupation.

4063. Refill of Prescription for Dangerous Drug or Device Requires Prescriber Authorization

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

4064. Emergency Refill of Prescription without Prescriber Authorization

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

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

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

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

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

4064.5. Dispensing a 90-Day Supply of a Dangerous Drug or Device; Requirements and Exceptions

(a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising their professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

(d) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(e) This section does not apply to FDA-approved, self-administered hormonal contraceptives.

(1) A pharmacist shall furnish or dispense, at a patient's request, up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills.

(2) Nothing in this subdivision shall be construed to require a pharmacist to dispense or furnish a drug if it would result in a violation of Section 733.

(g) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation

insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

4065. Injection Card System; Requirements for Administration

(a) "Injection card system," as used in this section, means a system that enables a facility to authorize an outpatient to receive injections of controlled substances at the facility pursuant to a prior written order by a physician, through the use of a card that is maintained at the location in the facility where the injections are administered.

(1) The injection card shall include, at a minimum, the following information: the date of authorization, the number and frequency of injections authorized, the name of the drug including the strength and amount authorized, the names of the prescribing physician and the patient, the date and time of each injection, and the signature of the person administering the injection.

(2) In addition, the patient's medical record maintained by the facility shall contain all of the information required under Sections 4040 and 4070 and Chapter 1 (commencing with Section 70001) of Division 5 of Title 22 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a licensed health care facility may provide for the administration of controlled substances through the use of an injection card system for controlled substances.

(c) A facility that employs an injection card system shall have a written protocol for the use of this system. The protocol shall be developed by a team of health care professionals, including at least one physician, one registered nurse, and one pharmacist. The protocol shall provide for, but not be limited to, the following:

(1) Identification of drugs to be included in the injection card system.

(2) Distinction among classes of drugs.

(3) Periodic review of the efficacy of the injection card system, including, but not limited to, its effectiveness and safety for different classes of drugs.

(4) Determination as to whether each drug included in the injection card system requires the presence of a physician or only the ready availability of a physician.

(5) Implementation of recordkeeping systems that, at a minimum, record each injection and each visit, provide for the immediate entry of the injection in the patient's medical record, provide a system for discontinuance of the order by the prescribing physician, and allow for ready identification of patterns of possible or actual patient abuse of controlled substances and other potential adverse drug interactions.

(6) Retention of the injection card by the facility at all times when a controlled substance is being administered.

(7) Adequate initial evaluation of patients, including, but not limited to, a determination as to whether each patient is a proper subject for the injection card system.

(8) Ongoing medical evaluation of the patient's response to the injection card system.

(9) That all injection cards shall become a permanent part of the patient's medical record within 15 days from the date the last authorized dose is administered.

(d) Nothing in this section shall be construed to prohibit the use, or impose new requirements on the use, of an injection card system for noncontrolled substances.

4066. Furnishing Dangerous Drugs to Master or First Officer of Vessel

(a) Notwithstanding Section 4059, a wholesaler or pharmacy may furnish dangerous drugs to the master or first officer of an ocean vessel, pursuant to a written prescription. The requisition shall be on the vessel's official stationery, signed by the vessel's first officer. The drugs shall be maintained on board the vessel and dispensed from medicine chests, first aid packets, or dispensaries, pursuant to standardized procedures established by a registered medical officer.

(b) Dangerous drugs shall be furnished in a sealed container to the vessel's first officer, on proper identification, or delivered aboard the vessel.

(c) Wholesalers or pharmacies engaging in the activities authorized by this section shall give notice to the board within 30 days of undertaking the activity.

(d) Distribution of controlled substances shall be in accordance with federal requirements contained in Section 1301.28 of Title 21 of the Code of Federal Regulations.

4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription

(a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to an appropriate prior examination of the human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to an appropriate prior examination of the human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the

person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(f) For the purposes of this section, "appropriate prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

4068. Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements

(a) Notwithstanding any provision of this chapter, except as provided in subdivision (b), a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply:

(1) The hospital pharmacy is closed and there is no pharmacist available in the hospital.

(2) The dangerous drug is acquired by the hospital pharmacy.

(3) The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.

(4) The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.

(5) The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

(6) The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services

outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.

(7) The prescriber shall ensure that the label on the drug contains all the information required by Section 4076.

(b) Notwithstanding any provision of this chapter, including subdivision (a), a prescriber may dispense an unused portion of a dangerous drug acquired by the hospital pharmacy to an emergency room patient upon discharge under all of the following conditions:

(1) The dangerous drug is not a controlled substance.

(2) The dangerous drug has been ordered and administered to the emergency room patient.

(3) The dangerous drug was administered from single patient use multidose packaging and can be self-administered by the patient, including, but not limited to, an inhaler, eye drop, ear drop, nose drop or spray, topical product, or liquid product.

(4) Dispensing the unused portion of the dangerous drug is required to continue treatment of the emergency room patient.

(5) The prescriber shall ensure that the label on the drug contains all of the information required by Section 4076.

(c) The prescriber shall be responsible for any error or omission related to the drugs dispensed.

4069. Dispensing or Furnishing a Dangerous Drug Pursuant to a Veterinary Prescription; Drug Documentation

A pharmacist who dispenses or furnishes a dangerous drug, as defined in Section 4022, pursuant to a veterinary prescription shall include, as part of the consultation, the option for a representative of an animal patient to also receive drug documentation specifically designed for veterinary drugs.

Article 4. Requirements for Prescriptions

4070. Reduction of Oral or Electronic Prescription to Writing

(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in

subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or

pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall impair the requirement to have an electronically transmitted prescription transmitted only to the pharmacy of the patient's choice or to have a written prescription. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

4071. Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

4071.1. Electronic Prescription Entry into Pharmacy or Hospital Computer

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500). This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(b) This section does not reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) A dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered

into a pharmacy's computer without the prior approval of a pharmacist.

(d)(1) A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures.

(2)(A) A health care facility shall maintain a record of a pharmacist's verification of medication chart orders pursuant to this subdivision.

(B) A record maintained pursuant to subparagraph (A) shall meet the same requirements as those described in Sections 4081 and 4105.

4072. Oral or Electronic Transmission of Prescription —Health Care Facility

(a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the Department of Public Health in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

4073. Substitution of Generic Drug —Requirements and Exceptions

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

4073.5. Substitution of Alternative Biological Product; Requirements and Exceptions

(a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

(1) The alternative biological product is interchangeable.

(2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision (d).

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one or more of the following electronic records systems:

(1) An interoperable electronic medical records system.

(2) An electronic prescribing technology.

(3) A pharmacy benefit management system.

(4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the

biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(e) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, “Do not substitute,” or words of similar meaning.

(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked “Do not substitute,” provided that the prescriber personally initials the box or checkmark.

(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as defined in subdivision (c) of Section 4040, a prescriber may indicate “Do not substitute,” or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription “Do not substitute.” In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this

subdivision, includes any professional fee that may be charged by the pharmacist.

(g) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

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

(1) “Biological product” has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).

(2) “Interchangeable” means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

(3) “Prescription,” with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

(l) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

(Added by Stats. 2015, Ch. 545, Sec. 1. Effective January 1, 2016.)

4074. Drug Risk: Informing Patient; Providing Consultation for Discharge Medications

(a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:

(1) The drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or the drug may impair a person's ability to drive a motor vehicle, whichever is applicable.

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

(c) The board may by regulation require additional information or labeling.

(d) This section shall not apply to a drug furnished to a patient in conjunction with treatment or emergency services provided in a health facility or, except as provided in subdivision (e), to a drug furnished to a patient pursuant to subdivision (a) of Section 4056.

(e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff.

Nothing in this subdivision or any other law shall be construed to require that only a pharmacist provide this consultation.

4075. Proof of Identity Required – Oral or Electronic Prescription

No prescription for a controlled substance transmitted by means of an oral or electronically transmitted order shall be furnished to any person unknown and unable to properly establish his or her identity. The board may by regulation establish procedures to prevent unauthorized persons from receiving prescription drugs furnished to a patient or a representative of the patient.

4076. Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to Section 4052 or pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized

procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to Section 4052 or pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in a commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation,

for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.
(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to Section 4052 or pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.
(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within the scope of practice.
(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.
(f)(1) Notwithstanding subdivision (a) or any other law, a pharmacist may dispense a drug prescribed pursuant to Section 120582 of the Health and Safety Code and label the drug without the name of an individual for whom the drug is intended if the

prescription includes the words “expedited partner therapy” or the letters “EPT.”

(2) A pharmacist who prescribes, dispenses, furnishes, or otherwise renders EPT, as authorized in subdivision (f), shall not be liable in, and shall not be subject to, a civil, criminal, or administrative action, sanction, or penalty for rendering EPT, if the use of EPT is in compliance with this section, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

(3) A pharmacist who provides EPT under this section shall provide written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.

(g)(1) Notwithstanding subdivision (a) or any other law, a pharmacist may, at their discretion, dispense brand name or generic mifepristone or any drug used for medication abortion without the name of the patient as required in paragraph (3) of subdivision (a), the name of the prescriber as required in paragraph (4) of subdivision (a), or the name and address of the pharmacy as required in paragraph (6) of subdivision (a) if the prescription is labeled with a prescription number or other means of identifying the prescription.

(2) A pharmacist who dispenses, furnishes, or otherwise renders brand name or generic mifepristone or any drug used for medication abortion, as authorized in paragraph (1), shall maintain a log with the prescription numbers and the information required in paragraphs (1) to (10), inclusive, of subdivision (a).

(3) Notwithstanding Section 4081, all records maintained under paragraph (2) shall not be open to inspection by law enforcement without a valid, court-issued subpoena.

(4) This subdivision does not prohibit the investigation of an activity that is punishable as a crime under the laws of this state, provided that records maintained under paragraph (2) are not shared with an individual or entity from another state.

(5) A pharmacist shall inform the patient that the pharmacist is dispensing brand name or generic mifepristone or any drug used for medication abortion as authorized by this subdivision.

4076.5. Standardized, Patient-Centered Prescription Labels; Requirements

(a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter

or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:

(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.

(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.

(C) The patient receives weekly or more frequent follow up contacts by a nurse or pharmacist.

(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

4076.6. Patient-Centered Prescription Labels; Translated Directions for Use; Requirements

(a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall provide translated directions for use in the languages the board has made available, but shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) A dispenser may provide their own translated directions for use to comply with the requirements of this section, and nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076.

(f) This section does not include prescriptions issued by a veterinarian.

4076.7. Caution Label Required for Drug Containing an Opioid

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

4076.8

(a) If a person informs a pharmacy that the person identifies as a person who is blind, has low-vision, or is otherwise print disabled, the dispenser shall provide to the person or their authorized representative, at no additional cost, an accessible prescription label affixed to the container that is all of the following:

(1) Available to the person in a timely manner comparable to other patient wait times and lasting for at least the duration of the prescription.

(2) Appropriate to the disability and language of the person making the request through use of audible, large print, Braille, or translated directions as required pursuant to Section 4076.6.

(3) Conforms to the format-specific best practices established by the United States Access Board and the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, also referred to as the National CLAS Standards.

(b) A dispenser shall ensure that the prescription label is compatible with the prescription reader if a reader is provided.

(c) If the accessible prescription label cannot be affixed to the container because it does not fit on the container, the dispenser, upon dispensing the prescription drug, shall provide the patient or their authorized representative with a supplemental document that meets the requirements specified in this section.

(d) This section does not apply to prescription drugs dispensed and administered by an institutional pharmacy, correctional institution, or licensed correctional pharmacy. However, this section does apply to an institutional pharmacy when providing prescription drugs to a person with a disability for use by the individual upon their release from the health care facility.

(e) This section does not include prescriptions issued by a veterinarian.

(f) The board shall promulgate regulations necessary to implement this section.

(g) As used in this section:

(1) “Institutional pharmacy” means a pharmacy that is part of, or is operated in conjunction with, a health care facility, as

defined in Section 1250 of the Health and Safety Code, with the exception of a licensed correctional pharmacy.

(2) “Prescription reader” means a device that is designed to audibly convey the information contained on the label of a prescription drug.

4077. Dispensing Dangerous Drug in Incorrectly Labeled Container

(a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

(b) Physicians, dentists, podiatrists, and veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug is properly labeled to show all information required in Section 4076 except the prescription number.

(c) Devices that bear the legend "Caution: federal law restricts this device to sale by or on the order of a _____," or words of similar meaning, are exempt from the requirements of Section 4076, and Section 111480 of the Health and Safety Code, when provided to patients in skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(d) The following notification shall be affixed to all quantities of dimethyl sulfoxide (DMSO) prescribed by a physician, or dispensed by a pharmacy pursuant to the order of a physician in California: "Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you."

(e) The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of reach of children.

4078. False or Misleading Label on Prescription

(a) (1) No person shall place a false or misleading label on a prescription.

(2) No prescriber shall direct that a prescription be labeled with any information that is false or misleading.

(b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances:

(1) If the labeling is a necessary part of a clinical or investigational drug program approved by the federal Food and Drug Administration or a legitimate investigational drug project involving a drug previously approved by the federal Food and Drug Administration.

(2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.

(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container.

4079. Availability of a Lower Retail Price for a Covered Drug

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

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

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

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

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

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

(g) This section shall become operative on January 1, 2020.

Article 5. Authority of Inspectors

4080. Stock of Dangerous Drugs and Devices Kept Open for Inspection

All stock of any dangerous drug or dangerous device or of shipments through a customs broker or carrier shall be, at all times during business hours, open to inspection by authorized officers of the law.

4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory; Nonprescription Diabetes Test Devices

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or

establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

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

(e)(1) In addition to the records described in subdivision (a), records that shall be maintained include policies and procedures related to pharmacy personnel and pharmacy operations. Such records shall be maintained in a readily retrievable format.

(2) Records described in paragraph (1) that are maintained electronically shall provide an audit trail for revisions and updates of each record.

(3) Prior versions of each electronically maintained record described in paragraph (2) shall be maintained in a readily retrievable format and include changes to the document, identification of the individual who made the change, and the date of each change.

4082. Names of Owners, Managers and Employees Open for Inspection

When called upon by an inspector, the owner or manager of any entity licensed by the board, or other store, shop, building, or premises retailing, wholesaling, or storing drugs or devices shall furnish the inspector with the names of the owner or owners, manager or managers, and employees together with a brief statement of the capacity in which these persons are employed on the premises.

4083. Orders of Correction

(a) An inspector may issue an order of correction to a licensee directing the licensee to comply with this chapter or regulations adopted pursuant to this chapter.

(b) The order of correction shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statute or regulations violated.

(c) The order of correction shall inform the licensee that within 30 days of service of the order of correction, the licensee may do either of the following:

(1) Submit a written request for an office conference with the board's executive officer to contest the order of correction.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the licensee's legal counsel or authorized representative may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the order of correction.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5

(commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the order of correction. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the order of correction.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the order of correction.

(2) Comply with the order of correction and submit a written corrective action plan to the inspector documenting compliance. If an office conference is not requested pursuant to this section, compliance with the order of correction shall not constitute an admission of the violation noted in the order of correction.

(d) The order of correction shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date of issuance of the order of correction.

(f) Nothing in this section shall in any way limit the board's authority or ability to do any of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Issue a letter of admonishment pursuant to Section 4315.

(3) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

(g) Unless a writ of mandate is filed, a citation issued, a letter of admonishment issued, or a disciplinary proceeding instituted, an order of correction shall not be considered a public record and shall not be disclosed pursuant to a request under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

4084. Adulterated, Misbranded or Counterfeit Dangerous Drug or Device

(a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.

(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.

(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.

(d) For the purposes of this article, "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.

(e) For the purposes of this article, "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(f) For the purposes of this article, "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

4084.1. Embargo of Nonprescription Diabetes Test Devices

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.

4085. Unlawful to Remove, Sell, or Dispose of Embargoed Dangerous Drugs or Dangerous Devices

(a) It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or dangerous device without permission of the board.

(b) When a board inspector has reasonable cause to believe, that the embargo will be violated, a board inspector may remove the embargoed dangerous drug or dangerous device from the premises.

4086. Adulterated or Counterfeit Dangerous Drug or Dangerous Device; Court Proceedings

(a) If a dangerous drug or dangerous device is alleged to be adulterated or counterfeit, the board shall commence proceedings in the superior court in whose jurisdiction the dangerous drug or dangerous device is located, for condemnation of the dangerous drug or dangerous device.

(b) If the court finds that an embargoed dangerous drug or dangerous device is adulterated or counterfeit, the dangerous drug or dangerous device shall, after entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of the board. All court costs and fees and all reasonable costs incurred by the board in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be paid by the claimant or owner of the dangerous drug or dangerous device.

(c) A superior court of this state may condemn any dangerous drug or dangerous device pursuant to this article. In the absence of an order, the dangerous drug or dangerous device may be destroyed under the supervision of the board who has the written consent of the owner, his or her attorney, or authorized representative. If the board cannot ascertain ownership of the dangerous drug or dangerous device within 30 days of establishing an embargo, the board may destroy the dangerous drug or dangerous device.

Article 6. General Requirements

4100. Change of Address or Name – Notification to Board

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-reverse distributor shall notify the executive officer of the board of the change of address or change of name.

4101. Pharmacist-in-Charge, Designated Representative-in-Charge: Termination of Employment; Notification to Board

(a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. A pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.

(b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer upon application by the wholesaler or veterinary food-animal drug retailer and approval by the board. A designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.

(c) A designated representative-3PL may take charge of, and act as, the responsible manager of a third-party logistics provider

upon application by the third-party logistics provider and approval by the board. A responsible manager who ceases to act as the responsible manager at that entity shall notify the board in writing within 30 days of the date of that change in status.

4102. Facility Self-Assessment

(a)(1) As provided in this section, all facilities licensed by the board shall complete the self-assessment process by July 1 of every odd-numbered year, unless otherwise established in this section.

(2) The self-assessment process shall be completed on a form provided by the board pursuant to this section.

(b) The form shall be completed to assess the facility's compliance with federal and state laws identified on the form. For each "no" response, the facility shall undertake a written corrective action or action plan to come into compliance with the law.

(c)(1) The form shall be signed under penalty of perjury by the designated individual, pursuant to this section, and cosigned by the owner or authorized officer of the facility acknowledging they have read, reviewed, and completed the self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the board.

(2) The completed form shall be kept on file in the facility and made available to the board or its designee upon request.

(d) The facility shall use the appropriate designated form based on the type of license, as described in this subdivision and as posted on the board's internet website.

(1) The Community Pharmacy Self-Assessment/Hospital Outpatient Self-Assessment form shall be completed by the pharmacist-in-charge. In addition to the requirements in subdivision (a), the form shall be completed within 30 days of any of the following:

(A) A new pharmacy license is issued.

(B) There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy.

(C) There is a change in the location of a pharmacy to a new address.

(2) The Hospital Pharmacy Self-Assessment form shall be completed by the pharmacist-in-charge. In addition to the requirements in subdivision (a), the form shall be completed within 30 days of any of the following:

(A) A new pharmacy license is issued.

(B) There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy.

(C) There is a change in the location of a pharmacy to a new address.

(3) The Automated Drug Delivery System Self-Assessment form shall be completed by the pharmacist-in-charge of the pharmacy operating the system. In addition to the requirements in subdivision (a), the form shall be completed within 30 days of any of the following:

(A) A new pharmacy license is issued.

(B) There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy.

(C) There is a change in the location of a pharmacy to a new address.

(4) The Compounding Self-Assessment form shall be completed by the pharmacist-in-charge of each pharmacy that compounds drug products. In addition to the requirements in subdivision (a), the form shall be completed within 30 days of any of the following:

(A) A new pharmacy license is issued.

(B) There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy.

(C) There is a change in the location of a pharmacy to a new address.

(5) The Surgical Clinic Self-Assessment form shall be completed by the consulting pharmacist of the surgical clinic and cosigned by the professional director.

(6) The Wholesaler/Third-Party Logistics Provider Self-Assessment form shall be completed by the designated representative-in-charge or the wholesaler or responsible

manager of the third-party logistics provider. In addition to the requirements in subdivision (a), the form shall be completed within 30 days of any of the following:

(A) A new license is issued.

(B) There is a change of designated representative-in-charge or responsible manager, and they become the new designated representative-in-charge or responsible manager.

(C) There is a change in the location to a new address.

(7) The Outsourcing Facility Self-Assessment form shall be completed by the designated quality control personnel. In addition to the requirements in subdivision (a), the form shall be completed within 30 days of any of the following:

(A) A new license is issued.

(B) There is a change in the designated quality control personnel.

(C) There is a change in the location to a new address.

4103. Blood Pressure—Taking by Pharmacist

Notwithstanding Section 2038, or any other provision of law, a pharmacist may take a person's blood pressure and may inform the person of the results, render an opinion as to whether the reading is within a high, low, or normal range, and may advise the person to consult a physician of the person's choice. Pharmacists rendering this service shall utilize commonly accepted community standards in rendering opinions and referring patients to physicians. Enforcement of this section is vested in the Board of Pharmacy of the State of California. Any pharmacist who performs this service shall not be in violation of Section 2052.

4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures

(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his

or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) The report required in subdivision (c) shall include sufficient detail to inform the board of the facts upon which the report is based, including an estimate of the type and quantity of all dangerous drugs involved, the timeframe over which the losses are suspected, and the date of the last controlled substances inventory. Upon request of the board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing.

(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to

participation in any administrative or judicial proceeding resulting from the report.

4105. Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

(a) All records or other documentation required to be maintained pursuant to this chapter by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this chapter shall be retained on the licensed premises for a period of three years from the date of making. Paper records may be converted into a digital format and maintained only in a noneditable format. Certification that the digitized documents have not been altered may be required by the board.

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy, digitized copy, or electronic copy of all records required by this chapter to be maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy, digitized copy, or electronic copy

of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

4106. License Verification Using Board Web Site

For purposes of license verification, a person may rely upon the licensing information as it is displayed on the board's Internet Web site that includes the issuance and expiration dates of any license issued by the board.

4107. One Site License per Premises; Exception

(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.

4107.5. Counterfeit Dangerous Drugs or Device; Fraudulent Transaction; Required Notice to Board

If a manufacturer, wholesaler, third-party logistics provider, or pharmacy has reasonable cause to believe that a dangerous drug or dangerous device in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, third-party logistics provider, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This section shall apply to any dangerous drug or dangerous device that has been sold or distributed in or through this state.

Article 7. Pharmacies

4110. License Required; Temporary Permit Upon Transfer of Ownership; Mobile Pharmacy Requirements

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

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

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

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

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

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

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

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

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

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

4110.5. Pharmacies: Mobile Units

Notwithstanding any other provision of this article, a county, city and county, or special hospital authority described in Chapter 5 (commencing with Section 101850) or Chapter 5.5 (commencing with Section 101852) of Part 4 of Division 101 of the Health and Safety Code may operate one or more mobile units to provide prescription medication within its jurisdiction to those individuals without fixed addresses, individuals living in county-owned or city-and-county-owned or operated housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code. The mobile unit shall be operated as an extension of a pharmacy license held by the county, city and county, or special hospital authority. The pharmacist-in-charge shall determine the number of mobile units that are appropriate for a particular pharmacy license. The mobile unit may dispense prescription medication pursuant to a valid prescription, including a prescription of a physician who practices in the mobile unit, if the county, city and county, or special hospital authority meets all of the following requirements:

(a) A licensed pharmacist is on the premises and the mobile unit is under the control and management of a pharmacist while prescription medications are being dispensed.

(b) All activities of the pharmacist, including the furnishing of medication by the pharmacist, are consistent with Article 3 (commencing with Section 4050).

(c) If a physician is practicing in the mobile unit, all prescribing by the physician meets the requirements of the Medical Practice Act (Chapter 5 (commencing with Section 2000)).

(d)(1) The mobile unit does not carry or dispense controlled substances.

(2) Paragraph (1) does not apply to Schedule III, Schedule IV, or Schedule V controlled substances approved by the United States Food and Drug Administration for the treatment of opioid use disorder. Any controlled substance for the treatment of opioid use disorder carried or dispensed in accordance with this paragraph shall be carried in reasonable quantities based on prescription volume and stored securely in the mobile pharmacy unit.

(e) Dangerous drugs shall not be left in the mobile unit during the hours that the mobile unit is not in operation.

(f) A county, city and county, or special hospital authority shall notify the board of its intention to operate a mobile unit as soon as possible, and no later than five business days after commencing operation of a mobile unit. A county, city and county, or special hospital authority shall also notify the board of its intention to discontinue operation of a mobile unit as soon as possible, and at least one business day before discontinuing operation of a mobile unit.

4111. Restrictions on Prescriber Ownership

(a) Except as otherwise provided in paragraph (2), or in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2)(A) Except as provided in subparagraph (B), a person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the license sought.

(B) Subparagraph (A) shall not preclude the issuance of a new or renewal license to conduct a pharmacy if both of the following conditions are met:

(i) Both the person or persons specified in paragraph (1) and the person seeking the license provide statements that the person or

persons specified in paragraph (1) disavow any community or financial interest in the license.

(ii) Any interest in the license that is shared community property, as defined in Section 65 of the Family Code, of a person specified in paragraph (1) and the person seeking the license is transmuted into the separate property of the person seeking the license.

(C) A pharmacy that is granted a license pursuant to the exception in subparagraph (B) shall not fill any prescriptions, emergency or otherwise, issued or prescribed by either of the following persons:

(i) A person specified in paragraph (1) who shares a community or other financial interest with the licensee.

(ii) A prescriber at the same place of business as a person specified in clause (i) if the prescriber owns an interest greater than 10 percent in the practice issuing the prescription.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e)(1) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist.

(2) If the board issues a license pursuant to paragraph (1), the pharmacist owning or owning and operating the pharmacy shall do both of the following when issuing a drug order pursuant to Section 4052, 4052.1, 4052.2, or 4052.6:

(A) Offer to provide a prescription to the patient that the patient may elect to have filled by a pharmacy of the patient's choice unless prohibited by the collaborative practice agreement.

(B) Provide a full patient consultation before issuing the drug order.

4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless they have obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the

nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers

controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

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

4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

(a) Any pharmacy located outside this state that is involved in the preparation, dispensing, shipping, mailing, or delivery, in any manner, of controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person shall not act as a nonresident pharmacy unless the person has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. The report shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board and ongoing licensure, the nonresident pharmacy shall identify a

California-licensed pharmacist employed and working at the nonresident pharmacy to be proposed to serve as the pharmacist-in-charge, and submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to California patients under either of the following conditions:

(1) The pharmacist's license has been revoked by the jurisdiction and has not been subsequently reinstated.

(2) The pharmacist-in-charge of the pharmacy is not licensed in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to

this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) The board may inspect a nonresident pharmacy licensed pursuant to this section. In addition to paying the fees established in Section 4400, the nonresident pharmacy shall deposit, when notified by the board, a reasonable amount, as determined by the board, necessary to cover the board's estimated reasonable costs of performing the inspection. If the required deposit is not received or if the actual costs of the inspection exceed the amount deposited, the board shall issue an invoice for the remaining amount and shall not take action on the renewal 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.

(l) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

(m) This section shall become operative on July 1, 2026.

4113. Pharmacist-in-Charge: Notification to Board; Responsibilities

(a)(1) Every pharmacy shall designate a pharmacist-in-charge.

(2) A pharmacy licensed pursuant to Section 4110 shall, within 30 days of the designation in paragraph (1), notify the board in writing of the identity and license number of that pharmacist and the date they were designated.

(3) A pharmacy licensed pursuant to Section 4112 shall, within 90 days of the designation in paragraph (1), notify the board in writing of the identify and license number of that pharmacist and the date they were designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c)(1) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(2) The pharmacist-in-charge shall make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. If the pharmacist-in-charge is not available, a pharmacist on duty may adjust staffing according to workload if needed. This paragraph does not apply to facilities of the Department of Corrections and Rehabilitation.

(3) The determination of the appropriate pharmacist-to-technician ratio shall be made by the pharmacist-in-charge, provided that the ratio does not exceed the maximum ratio established in subdivision (g) of Section 4115. No other person, permittee, or licensee shall interfere with the exercise of the pharmacist-in-charge's independent professional judgment in setting the pharmacist-to-technician ratio.

(d)(1) The pharmacist-in-charge or pharmacist on duty shall immediately notify store management or the building owner or a similar entity of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or

pharmacy staff. Store management shall take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the pharmacist-in-charge or pharmacist on duty shall ensure the board is timely notified.

(2) Nothing in this subdivision shall be construed as presenting, limiting, or restraining a pharmacist-in-charge, pharmacy technician, or member of the public from communication with the board, including filing a complaint.

(3) The conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:

(A) Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

(B) Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.

(C) Vermin infestation that poses a risk to the safety or efficacy of medicine.

(4) If, after receipt of a notice described in paragraph (1) and an evaluation and assessment of the relevant evidence, the executive officer has a reasonable belief that conditions within a pharmacy exist that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, the executive officer may, in conformance with the processes set forth in subdivisions (b) and (c) of Section 4127.3, issue an order to the pharmacy to immediately cease and desist those pharmacy operations that are affected by the conditions at issue. The cease and desist order shall remain in effect until either the executive officer determines the conditions that presented an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff have been abated or for no more than 30 days, whichever is earlier. Evidence of corrective actions taken shall be submitted by the pharmacy to correct the conditions at issue. Failure to comply with a cease and desist

order issued pursuant to this section shall be unprofessional conduct pursuant to Section 4156.

(5) Nothing in this paragraph shall prevent the owner of the licensed premises from closing a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

(6) Facilities of the Department of Corrections and Rehabilitation shall be exempt from this subdivision.

(e)(1) Every pharmacy licensed pursuant to Section 4110 shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge.

(2) Every pharmacy licensed pursuant to Section 4112 shall notify the board in writing, on a form designed by the board, within 90 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge.

(3) The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active

involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

4113.1. Reporting medication errors

(a) Except as specified in subdivision (e), a community pharmacy licensed pursuant to this article shall report, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the board. A community pharmacy shall submit the report no later than 14 days following the date of discovery of the error. These reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code), except that the board may publish deidentified case summary information compiled from the data in the reports so long as deidentification is done in accordance with the requirements set forth in Section 164.514(b)(2) of Title 45 of the Code of Federal Regulations, and includes omitting the name of the reporting pharmacy. The community pharmacy shall maintain records demonstrating compliance with this requirement for three years and shall make these records immediately available at the request of an inspector. A medication error report made pursuant to this section shall not be subject to investigation, discipline, or other enforcement action by the board based solely

on a report received pursuant to this section. However, if the board receives other information regarding the medication error independent of the medication error report, that information may serve as basis for discipline or other enforcement by the board.

(b) Any entity approved by the board shall have experience with the analysis of medication errors that occur in the outpatient setting.

(c) For purposes of this section, “community pharmacy” includes any pharmacy that dispenses medication to an outpatient, but does not include facilities of the Department of Corrections and Rehabilitation.

(d) For purposes of this section, “medication error” includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration. A medication error does not include any variation that is corrected prior to dispensing to the patient or patient’s agent or any variation allowed by law.

(e) An outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event, as specified in subdivision (a), that has been reported to the State Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code. The State Department of Public Health may share a report with the California State Board of Pharmacy.

(f) A pharmacy licensed pursuant to Section 4112 shall only be required to report medication errors related to prescriptions dispensed to California residents.

4113.5. Community Pharmacies: Required Staffing

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

the pharmacy is located, is made available to assist the pharmacist at all times.

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

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

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

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

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

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

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

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

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

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

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

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

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but

not limited to, illness, injury, family emergency, or the employee's termination or resignation.

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

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

4113.6. Staffing requirements for chain community pharmacy

(a) A chain community pharmacy subject to Section 4113.5 shall be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The board shall not take action against a pharmacy for a violation of this subdivision if any of the following conditions apply:

(1) The pharmacist on duty waives the requirement in writing during specified hours based on workload need.

(2) The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm. During the hours before 8:00 am and after 7:00 pm, the requirement shall not apply.

(3) The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), or any other ancillary services provided by law, this paragraph does not apply.

(b) Where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

(c) A chain community pharmacy shall post, in a prominent place for pharmacy personnel, a notice that provides information on how to file a complaint with the board.

4113.7. Prohibition on Quotas Related to Pharmacist or Pharmacy Technician Duties

(a) A chain community pharmacy, as defined in subdivision (c) of Section 4001, shall not establish a quota related to the duties for which a pharmacist or pharmacy technician license is required.

(b) A chain community pharmacy shall not, through employees, contractors, or third parties, communicate the existence of quotas, that are illegal pursuant to this section, to pharmacists or pharmacy technicians who are employees of the chain community pharmacy or with whom the chain community pharmacy contracts.

(c)(1) For purposes of this section, "quota" means a fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required, against which the chain community pharmacy or its agent measures or evaluates the number of times either an individual pharmacist or pharmacy technician performs tasks or provides services while on duty. "Quota" includes a fixed number or formula related to any of the following:

(A) Prescriptions filled.

(B) Services rendered to patients.

(C) Programs offered to patients.

(D) Revenue obtained.

(2) For purposes of this section, "quota" does not mean any of the following:

(A) A measurement of the revenue earned by a particular licensed chain community pharmacy not calculated in relation to, or measured by, the tasks performed, or services provided by, individual pharmacists or pharmacy technicians.

(B) Any evaluation or measurement of the competence, performance, or quality of care provided to patients of a pharmacist or pharmacy technician if the evaluation does not use quotas, as defined in paragraph (1).

(C) Any performance metric required by state or federal regulators that does not use quotas, as defined in paragraph (1).

(d) This section does not prohibit a chain community pharmacy from establishing policies and procedures that assist in assessing the competency and performance of a pharmacist or pharmacy technician in providing care to patients if the measurements used are not, or do not include, quotas, as defined in subdivision (c).

4114. Intern Pharmacist: Activities Permitted

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the direct supervision and control of a pharmacist whose license is in good standing with the board.

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

4115. Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratio

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b)(1) In addition to the tasks specified in subdivision (a), and where the pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a), a certified pharmacy technician as defined in Section 4202 may, under the direct supervision and control of a pharmacist, do any of the following:

(A) Prepare and administer influenza and COVID-19 vaccines via injection or intranasally, and prepare and administer epinephrine, provided that both of the following conditions are met:

(i) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's

injection technique prior to performing administration of vaccines.

(ii) The pharmacy technician is certified in basic life support.

(B)(i) Perform specimen collection for tests that are classified as CLIA.

(ii) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

(C) Initiate and receive prescription transfers and accept clarification on prescriptions.

(c) This section does not authorize the performance of any tasks specified in subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

f) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g)(1) A pharmacy with only one pharmacist shall have no more than three pharmacy technicians performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 3 to 1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional

facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the

discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

(k) Notwithstanding subdivision (a) of Section 4038, a pharmacy technician may, outside of a licensed pharmacy, do both of the following:

(1) Perform compounding activities only under the direct supervision and control of a pharmacist. The supervising pharmacist of the location where such compounding activities occur shall notify the board in writing.

(2) Administer vaccinations only under the direct supervision and control of a pharmacist.

4115.5. Pharmacy Technician Trainee; Placement; Supervision; Requirements

(a) Notwithstanding any other law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by the training program.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no fewer than 120 hours and no more than 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 340 hours.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in the training program.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates the pharmacy technician trainee's status as a trainee.

4116. Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

(b) (1) The board may, by regulation, establish reasonable security measures consistent with this section in order to prevent unauthorized persons from gaining access to the area, place, or premises or to the controlled substances or dangerous drugs or dangerous devices therein.

(2) The board shall, by regulation, establish conditions for the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing authorized personnel from the pharmacy. These

conditions shall ensure the security of the pharmacy and its operations during the temporary absence of the pharmacist and shall allow, at the discretion of the pharmacist, nonpharmacist personnel to remain and perform any lawful activities during the pharmacist's temporary absence.

4117. Admission to Area Where Narcotics are Stored, etc. – Who May Enter

No person other than a pharmacist, an intern pharmacist, a pharmacy technician, an authorized officer of the law, a person authorized to prescribe, a registered nurse, a licensed vocational nurse, a person who enters the pharmacy for purposes of receiving consultation from a pharmacist, or a person authorized by the pharmacist in charge to perform clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy shall be permitted in that area, place, or premises described in the license issued by the board to a licensed hospital wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.

4118. Waiving of Minimum Requirements by Board

(a) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements.

(b) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a hospital pharmacy, as defined by subdivision (a) of Section 4029, that does not meet all of the requirements for licensure as a hospital pharmacy, the board may waive any licensing requirements. However, when a waiver of any requirements is granted by the board, the pharmaceutical services to be rendered by this pharmacy shall be limited to patients registered for treatment in the hospital, whether or not

they are actually staying in the hospital, or to emergency cases under treatment in the hospital.

4118.5. Hospital Pharmacies: Medication Profiles or Lists for High-Risk Patients

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

(1) The hospital has more than 100 beds.

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

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

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

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

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

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

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

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

4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

(a) Notwithstanding any other 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 48.

(b) Notwithstanding any other 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 (Division 10 (commencing with Section 11000) of the Health and Safety Code).

4119.01. Emergency Medical Services Automated Drug Delivery Systems – Licensing; Fee; Restocking and Removing Drugs; Inventory and Reconciliation; Record keeping; Licensed Designated Paramedic

(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.

(c) This section shall be repealed on January 1, 2025.

4119.01. Emergency Medical Services Automated Drug Delivery Systems – Licensing; Fee; Restocking and Removing Drugs; Inventory and Reconciliation; Record keeping; Licensed Designated Paramedic

(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. 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.

(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.

(c) This section shall become operative on January 1, 2025.

4119.2. Furnish Epinephrine Auto-Injectors to School; Requirements

(a) Notwithstanding any other law, a pharmacy may furnish epinephrine delivery systems to a local educational agency pursuant to Section 49414 of the Education Code if all of the following are met:

(1) The epinephrine delivery systems are furnished exclusively for use at a local educational agency, as that term is defined in Section 49414 of the Education Code, including at any state or federally subsidized childcare program operated by or under contract with the local educational agency.

(2) A physician and surgeon provides a written order that specifies the quantity of epinephrine delivery systems to be furnished.

(b) Records regarding the acquisition and disposition of epinephrine delivery systems furnished pursuant to subdivision (a) shall be maintained by local educational agency for a period of three years from the date the records were created. The local educational agency shall be responsible for monitoring the supply of epinephrine delivery systems and ensuring the destruction of expired epinephrine delivery systems.

4119.3. Repackage Previously Dispensed Drug; Requirements

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.

(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:

(1) All the information required by Section 4076.

(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

4119.4. Epinephrine Auto-injector; Labeling; Records Requirements

(a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to an authorized entity, for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

(1) The epinephrine auto-injectors are furnished exclusively for use by, or in connection with, an authorized entity.

(2) An authorized health care provider provides a prescription that specifies the quantity of epinephrine auto-injectors to be furnished to an authorized entity described in subdivision (a) of Section 1797.197a of the Health and Safety Code. A new prescription shall be written for any additional epinephrine auto-injectors required for use.

(b) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:

(1) The name of the person or entity to whom the prescription was issued.

(2) The designations “Section 1797.197a Responder” and “First Aid Purposes Only.”

(3) The dosage, use, and expiration date.

(c) Each dispensed prescription shall include the manufacturer’s product information sheet for the epinephrine auto-injector.

(d) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by the authorized entity for a period of three years from the date the records were created. The authorized entity shall be responsible for monitoring the supply of

epinephrine auto-injectors and ensuring the destruction of expired epinephrine auto-injectors.

(e) The epinephrine auto-injector dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.

(f) For purposes of this section, "epinephrine auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.

4119.5. Transfer or Repackaging Dangerous Drugs by Pharmacy

(a) A pharmacy can transfer a reasonable supply of dangerous drugs to another pharmacy.

(b) A pharmacy may repackage and furnish to a prescriber a reasonable quantity of dangerous drugs and dangerous devices for prescriber office use.

4119.6. Health Care Facility; Stocking of Emergency Pharmaceutical Supplies Container and Emergency Medical System Supplies

An intern pharmacist under the direct supervision and control, as defined in Section 4023.5, of a pharmacist may stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code.

4119.7. Health Care Facility; Inspection of Drugs; Furnishing Per Standing Orders, etc.

(a) Notwithstanding any other law, a hospital pharmacy serving a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code may furnish a dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocols established under the policies and procedures of the health care facility, as approved according to the policies of the health care facility's governing

body, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device will be provided.

(b) A health care facility shall store and maintain drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. The health care facility's policies and procedures shall specify these storage parameters.

(c) An intern pharmacist under the direct supervision and control, as defined in Section 4023.5, of a pharmacist, may inspect the drugs maintained in the health care facility at least once per month. The health care facility shall establish specific written policies and procedures for inspections pursuant to this subdivision.

(d) For purposes of this section, "health care facility" means a health facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code.

4119.8. Naloxone Hydrochloride Furnished to School District, County Office of Education or Charter School; Records Requirements

(a) Notwithstanding any other law, a pharmacy may furnish naloxone hydrochloride or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code if all of the following are met:

(1) The naloxone hydrochloride or another opioid antagonist is furnished exclusively for use at a school district schoolsite, county office of education schoolsite, or charter school.

(2) A physician and surgeon provides a written order that specifies the quantity of naloxone hydrochloride or another opioid antagonist to be furnished.

(b) Records regarding the acquisition and disposition of naloxone hydrochloride or another opioid antagonist furnished pursuant to subdivision (a) shall be maintained by the school district, county office of education, or charter school for a period of three years from the date the records were created. The

school district, county office of education, or charter school shall be responsible for monitoring the supply of naloxone hydrochloride or another opioid antagonist and ensuring the destruction of expired naloxone hydrochloride or another opioid antagonist.

4119.9. Naloxone Hydrochloride Furnished to a Law Enforcement Agency

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

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

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

4119.10. Conditions Permitting Pharmacies to Perform CLIA-Waived Tests

A pharmacy located in the state may use pharmacists to perform FDA-approved or -authorized tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:

(a) The pharmacy is appropriately licensed as a laboratory under Section 1265.

(b) The pharmacy maintains policies and procedures that do all of the following:

(1) Establish the initial training requirements, including specimen collection techniques relevant to a test being performed at the pharmacy, and ongoing training.

(2) Establish safety precautions necessary to protect pharmacy staff and consumers and to reduce the risk of transmission, consistent with Cal-OSHA and CDC requirements, including, but not limited to, provisions for the use of personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements, and space requirements for pharmacy staff and consumers.

(3) Ensure the availability of dedicated physically distanced space or other segregated space that provides for privacy during the testing process and private consultation with the pharmacist, and limits potential contamination of other consumers in the pharmacy.

(4) Establish requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notifying the patient's health care providers if consent is provided, and referral to licensed sources of care for confirmation, diagnosis, and treatment as appropriate for follow-up to positive test results. A health care provider shall not be held personally liable for test results, or for any actions or inactions related to test results they did not receive, have knowledge of, or otherwise have access to.

(5) Establish requirements for the pharmacist-in-charge serving as the pharmacy laboratory director to report any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.

(6) Ensure documentation of testing equipment maintenance and calibration.

(7) Ensure appropriate storage and handling of specimens, testing reagents, and other supplies or equipment that require specialized storage or handling. Specimen collection shall not

include vaginal swab, venipuncture, or the collection of seminal fluid.
(c) The test is authorized to be administered by a pharmacist pursuant to paragraph (1) of subdivision (b) of Section 4052.4.
(d) The pharmacist-in-charge does both of the following:
(1) Annually reviews the policies and procedures maintained pursuant to subdivision (b), assesses the pharmacy's compliance with its policies, and documents corrective actions to be taken when noncompliance is found.
(2) Maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years from the date of completion.
(e) The pharmacy maintains documentation related to performing tests that demonstrates compliance with this section, which shall include the name of the pharmacist performing the test, the results of the test, and communication of results to a patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years from the date of creation.

4119.11. Automated Patient Dispensing Systems
(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:
(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300)

and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.

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

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

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

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

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

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

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

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the

automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years

after the last date of use of that automated patient dispensing system.
(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.
(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:
(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.
(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a

monthly basis, which shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(i) A pharmacy holding an automated patient dispensing system license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.
(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.
(k) This section shall be repealed on January 1, 2025.

4119.11. Automated Patient Dispensing Systems
(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:
(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.
(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.
(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.
(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.
(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.
(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.
(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.
(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.
(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.
(b) For purposes of this section, the following definitions shall apply:
(1) An “automated drug delivery system” (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2) An “automated patient dispensing system” (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.
(3) An “automated unit dose system” (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.
(c) (1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2) Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.
(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient, if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:
(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.
(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.
(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.
(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.
(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.
(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system if the automated patient dispensing system is disabled or malfunctions.
(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).
(3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.
(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.
(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.
(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.
(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.
(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.
(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.
(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.
(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password

system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.
(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:
(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.
(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.
(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.
(k) This section shall become operative on January 1, 2025.

4120. Nonresident Pharmacy: Registration Required

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler or third-party logistics provider who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler or third-party logistics provider pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

4121. Advertisement for Prescription Drug: Requirements; Restrictions

(a) Notwithstanding Section 651, an advertisement of the retail price for a drug that requires a prescription shall be limited to quantities of the drug that are consistent with good medical practice and shall include the strength, dosage form, and the exact dates during which the advertised price will be in effect.

(b) This section shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

4122. Required Notice of Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Price Information; Limitations on Price Information Requests

(a) In every pharmacy there shall be prominently posted in a place conspicuous to, and readable by, prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, the type of services provided by pharmacies, and a statement describing patients' rights relative to the requirements imposed on pharmacists pursuant to Section 733. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

4123. Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

4124. Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

(a) Notwithstanding Section 2543, a pharmacist may dispense replacement contact lenses pursuant to a valid prescription of a physician or optometrist. Nothing in this section authorizes a pharmacist to conduct an examination of the eyes or to fit or

adjust contact lenses. For purposes of this section, "replacement contact lenses" means soft contact lenses that require no fitting or adjustment, and that are dispensed as packaged and sealed by the manufacturer.

(b) No replacement contact lenses may be sold or dispensed except pursuant to a prescription that meets all of the following requirements:

(1) Conforms to state and federal statutes and regulations governing those prescriptions and includes the name, address, and state license number of the prescribing practitioner.

(2) Explicitly states an expiration date of not more than one year from the date of the last prescribing examination.

(3) Explicitly states that the prescription is for contact lenses and includes the lens brand name, type, and tint, including all specifications necessary for the ordering of lenses.

(c) The contact lenses that are dispensed shall be the exact contact lenses that have been prescribed, and no substitutions shall be made.

(d) Any pharmacist and pharmacy that dispenses replacement contact lenses shall direct the patient to confer with his or her eyecare practitioner in the event of any eye problem or reaction to the lenses.

(e) Any pharmacist and pharmacy that sells replacement contact lenses shall provide the following or substantially equivalent written notification to the patient whenever contact lenses are supplied:

WARNING: IF YOU ARE HAVING ANY UNEXPLAINED EYE DISCOMFORT, WATERING, VISION CHANGE, OR REDNESS, REMOVE YOUR LENSES IMMEDIATELY AND CONSULT YOUR EYE CARE PRACTITIONER BEFORE WEARING YOUR LENSES AGAIN.

(f) Any pharmacy and pharmacist dispensing replacement contact lenses shall be subject to all statutes, regulations, and ordinances governing the advertisement of contact lenses. In addition, any advertisement by a pharmacy or pharmacist that mentions replacement contact lenses shall include within the

advertisement all fees, charges, and costs associated with the purchase of the lenses from that pharmacy and pharmacist.

(g) Any pharmacy dispensing replacement contact lenses shall register with the Medical Board of California at the time of initial application for a license or at the time of annual renewal of that license.

(h) All nonresident pharmacies shall maintain records of replacement contact lenses shipped, mailed, or delivered to persons in California for a period of at least three years. The records shall be available for inspection upon request by the board or the Division of Licensing of the Medical Board of California.

(i) The requirements of this section are applicable to nonresident pharmacies as defined in subdivision (a) of Section 4112. A nonresident pharmacy may dispense contact lenses only as provided in this section.

4125. Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall

affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

4126. Covered Entity May Contract With Pharmacy to Provide Pharmacy Services; Segregation of Drug Stock; Return of Drugs Not Dispensed; Wholesale License Not Permitted or Required

(a) Notwithstanding any other provision of law, a covered entity may contract with a pharmacy to provide pharmacy services to patients of the covered entity, as defined in Section 256b of Title 42 of the United States Code, including dispensing preferentially priced drugs obtained pursuant to Section 256b of Title 42 of the United States Code. Contracts between those covered entities and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

(b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy's other drug stock by either physical or electronic means. All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records.

(c) Drugs obtained by a pharmacy to be dispensed to patients of a covered entity pursuant to Section 256b of Title 42 of the United States Code that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy shall be returned to the distributor from which they were obtained. For the purposes of this section, a change in circumstances includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity.

(d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license.

(e) Neither a covered entity nor a pharmacy shall be required to obtain a license as a wholesaler based on acts reasonably necessary to fully participate in the drug purchase program established by Section 256b of Title 42 of the United States Code.

4126.5. Furnishing Dangerous Drugs by Pharmacy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4126.8 Compounding Consistent with United States Pharmacopeia – National Formulary

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

4126.9. Recall of Nonsterile Compounded Drug Products – Requirements

(a) A pharmacy that issues a recall notice regarding a nonsterile compounded drug product shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

(c) A pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy shall report the event to MedWatch within 72 hours of the pharmacy being advised.

4126.10. Reporting Requirements for Interstate Distribution of Compounded Human Drug Preparations

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

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

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

(3) The pharmacy reports any adverse drug experience and product quality issue for any compounded product to the board

within 12 hours after the pharmacy receives notice of the adverse drug experience or product quality issue.
(b) Information reported by the board to the FDA directly or through the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the FDA to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products shall not be subject to public disclosure under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code).

Article 7.5 Compounded Sterile Drug Products

4127. License to Compound Sterile Drug Products Required

(a) A pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article.

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

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

4127.1. License for Compounding Sterile Drug Products; Requirements; Exceptions

(a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be

issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

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

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.

(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

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

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(h) This section shall become operative on July 1, 2014.

4127.2. Nonresident Pharmacy License for Compounding and Shipping Sterile Drug Products into California; Requirements; Adverse Effects Reporting

(a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

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

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.

(4) Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

(4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration

or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

(i) This section shall become operative on July 1, 2014.

4127.3. Cease and Desist Order; Hearing

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

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

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

the board pursuant to Section 1094.5 of the Code of Civil Procedure.
(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4127.4. Fine for Violation

Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars ($2,500) per occurrence pursuant to a citation issued by the board.

4127.6. Article Operative Upon Allocation of Positions

This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.

4127.7. Temporary License to Compound Injectables

The board may, at its discretion, issue a temporary license to compound sterile drug products upon the conditions and for any 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 (u) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary 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 comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

4127.8. Pharmacies That Compound Sterile Drug Products; Recalls; Requirements

(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

4127.15. Hospital Satellite Compounding Pharmacy

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.

Article 7.6.
Centralized Hospital Packaging Pharmacies

4128. Centralized Hospital Packaging

(a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.

(2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

(b) For purposes of this article, “common ownership” means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

4128.2. Specialty License Required; Application; Fees

(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) Until July 1, 2017, the fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars ($600) and may be increased by the board to eight hundred dollars ($800).

(i) This section shall be repealed on January 1, 2025.

4128.2. Specialty License Required; Application; Fees

(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) This section shall become operative on January 1, 2025.

4128.3. Preparing and Storing Limited Quantity of Unit Dose Drugs in Advance of a Patient-Specific Prescription

A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of inpatients of the general acute care hospital based on a documented history of prescriptions for that patient population.

4128.4. Barcode Required; Information Retrievable Upon Reading Barcode *(Effective September 2, 2015)*

(a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient's bedside using barcode medication administration software.

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.

4128.5. Labeling for Unit Dose Medications

(a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall display a human-readable label that contains all of the following:

(1) The date that the medication was prepared.

(2) The beyond-use date.

(3) The established name of the drug.

(4) The quantity of each active ingredient.

(5) Special storage or handling requirements.

(6) The lot number or control number assigned by the centralized hospital packaging pharmacy.

(7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

(1) The components used in the drug product.

(2) The expiration date of each of the drug's components.

(3) The National Drug Code Directory number.

(Amended by Stats. 2015, Ch. 241, Sec. 3. Effective September 2, 2015.)

4128.6. Compounding

All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile compounding.

4128.7. Integrity, Potency, Quality and Labeled Strength of Unit Dose Drug Products

A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

Article 7.7. Outsourcing Facilities

4129. Outsourcing Facility – License Required

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

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

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

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

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

4129.1. Licensing Requirements

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

4129.2. Nonresident Outsourcing Facility – License Required

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) (A) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(B) For purposes of this paragraph, “state” refers to the state in which the nonresident outsourcing facility resides.

(3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

(e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.

(3) A copy of any complaint it receives involving an outsourcing facility’s compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility’s products.

4129.3. Board Report to Legislature

(a) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident outsourcing facilities. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident outsourcing facilities.

(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board’s activities related to the inspection and licensure of nonresident outsourcing facilities.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules,

regulations or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

4129.4. Cease and Desist Order

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

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

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

or control of the outsourcing facility may seek review of the decision pursuant to Section 1094.5 of the Code of Civil Procedure.
(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4129.5. Violation Fine

Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars ($5,000) per occurrence pursuant to a citation issued by the board.

4129.8. Temporary License

The board, at its discretion, may issue a temporary license to an outsourcing facility upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

4129.9. Recall – Notice Required

(a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber and the prescriber shall ensure the patient is notified.

(2) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy and that pharmacy shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

Article 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies

4130. Remote Dispensing Site Pharmacy – Use of Telepharmacy System; Medically Underserved Areas; Staffing; Transition to Full-Service Pharmacy

(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.

4131. Remote Dispensing Site Pharmacy – Distance from Supervising Pharmacy; Common Ownership; Staffing by Pharmacy Technician; Pharmacist-in-Charge

(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.

4132. Remote Dispensing Site Pharmacy – Pharmacy Technician: Permitted Duties; Prohibited Duties; Pharmacist-to-Pharmacy Technician Ratio

(a) In addition to the requirements of Section 4202, a pharmacy technician shall satisfy each of the following requirements before working at a remote dispensing site pharmacy.

(1) Possess a pharmacy technician license that is in good standing.

(2) Possess and maintain a certification issued by a board-approved pharmacy technician certification program.

(3) Possess one of the following:

(A) A minimum of an associate degree in pharmacy technology.

(B) A minimum of a bachelor's degree in any subject.

(C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.

(4) Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

(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.

4133. Telepharmacy System – Audio-Visual System; Use in Patient Counseling; System Capabilities; Recordkeeping

(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.

4134. Remote Dispensing Site Pharmacy – Pharmacist Inspection; Perpetual Inventory; Securing Controlled Substances; Inventory and Reconciliation; Controlled Substances Inventory; Requirement to Report Losses

(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.

4135. Remote Dispensing Site Pharmacy – Alarm Required; Closed When Supervising Pharmacy Is Closed; Maintaining Surveillance Recording

(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.

Article 9. Hypodermic Needles and Syringes

4141. Furnishing without License

No person shall furnish hypodermic needles or syringes, by sale or otherwise, without a license issued by the board, except as otherwise provided by this article.

4143. Exemption: Sale to Other Entity, Physician, etc.

This article shall not apply to the sale of hypodermic syringes and needles at wholesale by pharmacies, drug wholesalers, drug manufacturers or manufacturers and dealers in surgical instruments to pharmacies, physicians, dentists, podiatrists, veterinarians, or persons to whom a license has been issued under this article.

4144.5. Industrial Use; Exception

A person may sell or obtain hypodermic needles and hypodermic syringes without a prescription or permit, for uses that the board determines are industrial, and that person shall not be required to comply with Section 4145.5 or 4146.

4145.5. Conditions for Furnishing Hypodermic and Syringes for Human Use and Specified Animal Use without a Prescription

(a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons,

a physician or pharmacist may, without a prescription or a permit, furnish hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on a (d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall counsel consumers on safe disposal and provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(2) It shall furnish, or make available, mail-back sharps containers authorized by the United States Postal Service that meet applicable state and federal requirements for the transport of medical sharps waste, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(f) A pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at

the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

4146. Needle/Syringe Return in Sharps Container

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container, as defined in Section 117750 of the Health and Safety Code.

4147. Disposal of Needle or Syringe

(a) For the purposes of this section, "playground" means any park or outdoor recreational area specifically designed to be used by children that has play equipment installed or any similar facility located on public or private school grounds or county parks.

(b) Any hypodermic needle or syringe that is to be disposed of, shall be contained, treated, and disposed of, pursuant to Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code.

(c) It is unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school.

(d) A person who knowingly violates subdivision (c) is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than two hundred dollars ($200) and not more than two thousand dollars ($2,000), or by imprisonment in a county jail for up to six months, or by both that fine and imprisonment.

(e) Subdivision (c) does not apply to the containment, treatment, and disposal of medical sharps waste from medical care or first aid services rendered on school grounds, nor to the containment, treatment, and disposal of hypodermic needles or syringes used for instructional or educational purposes on school grounds.

4148.5. Confiscation if Found Outside Licensed Premises

All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144.5, or 4145.5, or under Section 11364, 121349, or 121349.1 of the Health and Safety Code.

4149. License Required for Nonresident Distributor of Needles or Syringes

(a) A nonresident distributor shall not sell or distribute hypodermic needles or syringes in this state without obtaining a license from the board pursuant to Section 4141.

(b) Notwithstanding subdivision (a), a license is not required if the nonresident distributor sells or distributes solely through a person who is licensed as a wholesaler or third-party logistics provider pursuant to Section 4160.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident distributor pursuant to this article to serve as evidence that the entity is doing business within this state.

Article 10. Pharmacy Corporations

4150. Definitions

(a) A pharmacy corporation means a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, so long as that corporation and its shareholders, officers, directors, and employees rendering professional services who are pharmacists are in compliance with the Moscone-Knox Professional Corporation Act, this article, and all other statutes and regulations now or hereafter enacted or adopted pertaining to the corporation and the conduct of its affairs.

(b) With respect to a pharmacy corporation, the governmental agency referred to in the Moscone-Knox Professional

Corporation Act is the Board of Pharmacy of the State of California.

4151. Licensure Requirements

Each shareholder, director, and officer of a pharmacy corporation, except an assistant secretary and an assistant treasurer, shall be a licensed person as defined in Section 13401 of the Corporations Code.

4152. Corporate Name Requirements

The name of a pharmacy corporation and any name or names under which it may render professional services shall contain the word "pharmacist," "pharmacy," or "pharmaceutical" and wording or abbreviations denoting corporate existence.

4153. Shareholder Income While Disqualified

The income of a pharmacy corporation attributable to professional services rendered while a shareholder is a disqualified person, as defined in Section 13401 of the Corporations Code, shall not in any manner accrue to the benefit of the shareholder or his or her shares in the pharmacy corporation.

4154. Regulations Authorized

The board may adopt and enforce regulations to carry out the purposes and objectives of this article, including regulations requiring (a) that the bylaws of a pharmacy corporation shall include a provision whereby the capital stock of the corporation owned by a disqualified person, as defined in Section 13401 of the Corporations Code, or a deceased person, shall be sold to the corporation or to the remaining shareholders of the corporation within the time as the regulations may provide, and (b) that a pharmacy corporation shall provide adequate security by insurance or otherwise for claims against it by its patients or clients arising out of the rendering of professional services.

4155. Corporate Form Not Required

Nothing in this article shall be construed as requiring the applicant or holder of a pharmacy permit pursuant to Section 4110 to be a pharmacy corporation.

4156. Unprofessional Conduct by Corporation

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

Article 11. Wholesalers, Third-Party Logistics Providers and Manufacturers

4160. Wholesaler or Third-Party Logistics Provider: License Required

(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 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. For purposes of retaining a temporary license, or for purposes of any disciplinary or license denial proceeding before the board, the

temporary licenseholder shall not be deemed to have a vested property right or interest in the license.

4160.5. Nonprescription Diabetes Test Devices – Authorized Distributors Posted on Board Website

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.

4161. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Requirements

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

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

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

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

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

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

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

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

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

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

(G) The wholesaler is not acting as a reverse distributor.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and

any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.

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

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

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws

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

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a

temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.
(m) This section shall be repealed on January 1, 2025.

4161. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Requirements
(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.
(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.
(c)(1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this

state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.
(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:
(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.
(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.
(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.
(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.
(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.
(F) The third-party logistics provider is not a reverse third-party logistics provider.
(G) The wholesaler is not acting as a reverse distributor.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident

third-party logistics provider license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred

by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.
(i)(1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.
(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a

temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.
(m) This section shall become operative on January 1, 2025.

4161.5. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider

At such time as federal regulations are promulgated to implement Section 584 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360eee-3), the board shall immediately identify any standard, requirement, or regulation in California law governing interstate commerce that is in conflict with the federal regulations and act to remove the conflict in the manner permitted by law.

4162. Wholesaler or Third-Party Logistics Provider; Surety Bond Requirements

(a) (1) An applicant for the issuance or renewal of a wholesaler license, which is not government owned and operated, shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a third-party logistics provider license, which is not government owned and operated, shall submit a surety bond of ninety thousand dollars ($90,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(3) For purposes of paragraphs (1) and (2), the board may accept a surety bond less than the amount required under paragraph (1) or (2) if the annual gross receipts of the previous tax year for the wholesaler or third-party logistics provider is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(4) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler or third-party logistics provider, shall not be required to post a surety bond as provided in paragraph (1) or (2).

(5) For licensees subject to paragraph (3) or (4), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

4162.5. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Surety Bond Requirements

(a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a nonresident third-party logistics provider license shall submit a surety bond of ninety thousand dollars ($90,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(3) For purposes of paragraphs (1) and (2), the board may accept a surety bond less than the amount required under paragraph (1) or (2) if the annual gross receipts of the previous tax year for the nonresident wholesaler or the nonresident third-party logistics provider is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(4) For applicants who satisfy paragraph (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler or nonresident third-party logistics provider who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(5) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler or a nonresident third-party logistics provider, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

4163. Unauthorized Furnishing by Manufacturer or Wholesaler

(a) A manufacturer, wholesaler, repackager, or pharmacy shall not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Except as provided in subdivision (c), drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Upon approval of the board, a reverse distributor licensed as a wholesaler may acquire a dangerous drug or dangerous device from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drug or dangerous device.

4164. Reports Required

(a) A wholesaler or third-party logistics provider licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all distributions of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, "preferential or contract prices" means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

4165. Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand

A wholesaler or third-party logistics provider licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

4166. Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor Liable for Security and Integrity Until Delivery

(a) A wholesaler that uses the services of a third-party logistics provider or carrier, including, but not limited to, the United States Postal Service or a common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that provider or carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) A third-party logistics provider that uses the services of a carrier, including, but not limited to, the United States Postal Service or a common carrier, shall have in place and comply with written policies and procedures that provide for both of the following:

(1) Verification that the third-party logistics provider, or the owner of the dangerous drugs or dangerous devices stored at the third-party logistics provider, has imposed obligations on the carrier that provide for the security and integrity of any

dangerous drugs or dangerous devices transported by the carrier until the drugs or devices are delivered to the transferee at its premises.

(2) Confirmation, prior to shipping a dangerous drug or dangerous device, that the intended recipient is legally authorized to receive the dangerous drug or dangerous device.

(c) Nothing in this section is intended to affect the liability of a wholesaler, third-party logistics provider, or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

4167. Wholesaler or Third-Party Logistics Provider: Bar on Obtaining Dangerous Drugs or Devices it Cannot Securely Maintain on Licensed Premises

A wholesaler or third-party logistics provider shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, at the place of business licensed by the board.

4168. Board License Required for Local Business License

A county or municipality shall not issue a business license for any establishment that requires a wholesaler or third-party logistics provider license unless the establishment possesses a current wholesaler or third-party logistics provider license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

4169. Prohibited Acts

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

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

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

4169.1. Wholesaler Obligation to Report Suspicious Orders to Board

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.

Article 11.5. Surplus Medication Collection and Distribution Intermediaries

4169.5. Surplus medication Collection and Distribution Intermediary; License

(a) A surplus medication collection and distribution intermediary established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a program established pursuant to Division 116 (commencing with Section 150200) of the Health and Safety Code shall be licensed by the board. The board shall enforce the requirements set forth in Section 150208 of the Health and Safety Code. The license shall be renewed annually.

(b) An application for licensure as a surplus medication collection and distribution intermediary shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is an entity other than a natural person, the application shall state the information as to each person beneficially interested in that entity.

(c) As used in this section, and subject to subdivision (e), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(d) If the applicant is a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, the applicant shall furnish the board with the organization's articles of incorporation. The applicant shall also furnish the board with the names of the controlling members.

(e) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and if the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (b) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant's entity. Upon request by the executive officer of the board, the applicant shall furnish the board with the information required by subdivision (b) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(f) The application shall contain a statement to the effect that the applicant or persons beneficially interested have not been convicted of a felony and have not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(g) Upon the approval of the application by the board and payment of a fee in the amount of three hundred dollars ($300), the executive officer of the board shall issue or renew a license to operate as a surplus medication collection and distribution intermediary, if all of the provisions of this chapter have been complied with. Fees received by the board pursuant to this section shall be deposited into the Pharmacy Board Contingent Fund. An applicant for licensure as a surplus medication collection and distribution intermediary that is government owned or is a nonprofit organization pursuant to subdivision (d) is exempt from the fee requirement.

(h) A surplus medication collection and distribution intermediary licensed pursuant to this section is exempt from licensure as a wholesaler.

(i) A surplus medication collection and distribution intermediary licensed pursuant to this section shall keep and maintain for three years complete records for which the intermediary

facilitated the donation of medications to or transfer of medications between participating entities.

Article 11.7 Cancer Medication Collection and Distribution: Registry of Participating Practitioners

4169.7. Requirements for Participating in Registry

(a) A participating practitioner in the collection and distribution of unused cancer medications pursuant to the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code shall be registered with a surplus medication collection and distribution intermediary, as defined in Section 150401 of the Health and Safety Code, in accordance with this section. The registration shall be renewed annually.

(b) An application for registration with a surplus medication collection and distribution intermediary shall be made on a form, which may be in an electronic format, furnished by the surplus medication collection and distribution intermediary, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant.

(c) Upon the approval of an application by a surplus medication collection and distribution intermediary, and payment of a fee in an amount not to exceed three hundred dollars ($300) to the surplus medication collection and distribution intermediary for processing the application and issuing or renewing the registration, the surplus medication collection and distribution intermediary shall issue or renew a registration certificate to operate as a participating practitioner, if the practitioner has complied with all of the provisions of this chapter.

(d) A surplus medication collection and distribution intermediary shall do all of the following:

(1) Create a registry, not to exceed 50 participating practitioners.

(2) Develop a donor form that may be in an electronic format and that shall include all of the following information:

(A) The date the medication was donated.

(B) The name, address, and telephone number of the donor.

(C) The name, strength, and quantity of the medication.

(D) The manufacturer and lot number, if applicable, of the medication.

(E) The name and dated signature of the practitioner who is accepting and inspecting the donated medication.

(F) An acknowledgment that the medication was handled and stored in accordance with the physician's order and per the manufacturer's recommendation.

(3) Develop a recipient form, which may be in an electronic format, and which shall include all of the following:

(A) The date the recipient received the medication.

(B) The name, address, and telephone number of the recipient.

(C) The name, strength, and quantity of the medication.

(D) The manufacturer and the lot number, if applicable, of the medication.

(E) The name and dated signature of the practitioner who is accepting and inspecting the donated medication.

(F) An acknowledgment that the donor is known to the practitioner and is a patient of record, and that there is no reason to believe that the donated prescription medication was improperly handled or stored.

(G) An acknowledgment that by accepting the donated prescription medication, the recipient accepts any risks that an accidental mishandling could create.

(H) An acknowledgment that the donor, the participating practitioner, and the surplus medication collection and distribution intermediary are released from liability arising from their participation pursuant to this article and the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code.

(I) An acknowledgment that the pharmaceutical manufacturer is released from liability of any claims or injury arising from the transfer of any prescription medication pursuant to this article and the program established pursuant to Division 117

(commencing with Section 150400) of the Health and Safety Code.

(J) An acknowledgment that the recipient is receiving donated prescription medication and that the recipient is receiving the donated prescription medication at no cost.

(e) A participating practitioner is exempt from licensure as a wholesaler.

(f) A participating practitioner shall keep and maintain for three years records created by the participating practitioner for purposes of this article.

(g) The board may request records from the distribution intermediary and participating practitioner to confirm compliance with this section and Section 150400 of the Health and Safety Code.

(h) The board may prohibit a participating practitioner from participating in the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code if the participating practitioner does not comply with the requirements of the program or this article. If the board prohibits a participating practitioner from participating in the program, it shall, within 15 days of making that determination, provide written notice to the participating practitioner and to the surplus medication collection and distribution intermediary that issued the participating practitioner a registration certificate to operate as a participating practitioner.

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

(1) “Donor” means an individual who donates unused prescription medications to a participating practitioner for the purpose of redistribution to established patients of that practitioner.

(2) “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code. “Ineligible drugs” include all controlled substances, including all opioids, all compounded medications, injectable medications, drugs that have an approved United States Food and Drug Administration Risk

Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.

(3) “Participating practitioner” means a person who is licensed to practice medicine by the Medical Board of California and is board certified in medical oncology or hematology and is registered with a surplus medication collection and distribution intermediary.

(4) “Recipient” means an individual who voluntarily receives donated prescription medications.

(5) “Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” as defined in Section 4022 or a “drug” as defined in Section 4025, that is prescribed as part of a cancer treatment plan and is in its original unopened, tamper-evident dose unit packaging that includes the drug’s lot number and expiration date. A cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened.

4169.8. Article Repeal Date

This article shall remain in effect only until January 1, 2027, and as of that date is repealed.

Article 12. Prescriber Dispensing

4170. Dispensing by Prescriber: Requirements and Restrictions; Enforcement

(a) A prescriber shall not dispense drugs or dangerous devices to patients in the prescriber’s 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 the prescriber 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, before 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.

(b) A certified nurse-midwife who functions pursuant to a mutually agreed-upon policy or protocol described in Section 2746.5, 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.

(c) The Medical Board of California, the State Board of Optometry, the California Board of Naturopathic Medicine, the Dental Board of California, the Podiatric Medical Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Board 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.

(d) "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, a certificate to practice podiatry, or a certificate to practice as a nurse practitioner practicing pursuant to Section 2837.103 and 2837.104, or a certificate to practice as a nurse-midwife, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, the California Board of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, the Podiatric Medical Board of California, or the Board of Registered Nursing.

4170.5. Veterinarian in Teaching Hospital May Dispense and Administer Dangerous Drugs and Devices; Requirements

(a) Veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school may dispense and administer dangerous drugs and devices and controlled substances from a common stock.

(b) The veterinary teaching hospital shall designate a pharmacist to be responsible for ordering the drugs for the common stock and the designated pharmacist-in-charge shall be professionally responsible to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, and dispensing occur in a manner that is consistent with the promotion and protection of the health and safety of the public.

(c) The veterinary teaching hospital's pharmacist-in-charge shall develop policies, procedures, and guidelines that recognize the unique relationship between the institution's pharmacists and veterinarians in the control, management, dispensation, and administration of drugs.

(d) The board may inspect a veterinary teaching hospital dispensing or administering drugs pursuant to this section.

4171. Exceptions to Section 4170: Samples; Clinics; Veterinarians; Narcotic Treatment Programs; Certain Cancer Medications

(a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

4172. Storage Requirements

A prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be dispensed in an area that is secure. The Medical Board of California shall, by regulation, define the term "secure" for purposes of this section.

4173. Dispensing by Registered Nurses

This chapter does not prevent the dispensing of drugs or devices by registered nurses functioning pursuant to Section 2725.1.

4174. Dispensing by Pharmacist Upon Order of Nurse Practitioner

Notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner practicing pursuant to Section 2836.1, 2837.103, 2837.104, or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052, 4052.04, 4052.1, 4052.2, or 4052.6.

4175. Processing of Complaints

(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 Board, 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.

Article 13. Nonprofit or Free Clinics

4180. Purchase of Drugs at Wholesale Only with License: Eligible Clinics

(a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than the number of hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

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

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

(c) The board shall synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

4181. License Requirements; Policies and Procedures; Who May Dispense

(a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of

the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. Duties of Professional Director; Consulting Pharmacist Required

(a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

4183. No Professional Dispensing Fee

No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. Dispensing Schedule II Substance by Clinic Prohibited

(a) Except as described in subdivision (b), a Schedule II controlled substance shall not be dispensed by the clinic. This limitation does not prohibit a physician dispensing a Schedule II drug to the extent permitted by law.

(b) A practitioner authorized to prescribe a narcotic drug at a clinic registered with the board pursuant to this chapter and with any necessary federal agencies may dispense that narcotic drug from clinic supply for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment consistent with Section 1306.07(b) of Title 21 of the Code of Federal Regulations.

(c) A narcotic drug that is dispensed from a clinic's supply pursuant to subdivision (b) is subject to the requirements of subdivision (d) of Section 11165 of the Health and Safety Code, the labeling requirements imposed upon pharmacists by Section 4076, the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including, but not limited to, the use of childproof containers.

(d) A clinic with a supply of narcotic drugs that is being dispensed pursuant to subdivision (b) shall establish policies or procedures for dispensing, including, but not limited to, all of the following:

(1) Assessment of the patient's ability to safely manage and self-administer a narcotic drug for the purposes of treating withdrawal.

(2) Assessment of the patient's appropriateness for medications for opioid use disorder.

(3) Connecting patients to ongoing treatment for opioid use disorder.

(4) Limiting dispensing to patients who return for repeated withdrawal medication to ensure treatment is not renewed or extended.

(e) The dispensing of a narcotic drug shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

(f) It is the intent of the Legislature that a clinic from which narcotic drugs are dispensed operate under appropriate registration and licensing and prioritize safe and secure storage, including any inventory reconciliation methodology, consistent with regulations, to prevent loss or diversion of controlled substances.

4185. Inspection Permitted

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

4186. Automated Drug Delivery Systems

(a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

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

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.
(h) This section shall become operative on July 1, 2019.

Article 13.5. Correctional Clinics

4187. Correctional Clinics

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

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

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

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

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

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

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

4187.1. Correctional Clinics: Licensing; Dispensing and Administering of Drugs

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

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

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

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

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

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

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

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

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

4187.2. Correctional Clinics: Policies and Procedures

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

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

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

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

4187.3. Correctional Clinics: Administering Controlled Substances

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

4187.4. Correctional Clinics: Board Inspections

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

4187.5 Correctional Clinics: Automated Drug Delivery Systems

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

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

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

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

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

(1) A pharmacist.

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

(e) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the correctional clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

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

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

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

dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

Article 14. Clinics

4190. Clinic Defined; License Required; Purchase of Drugs at Wholesale: Drug Distribution Service of a Clinic; Information Reported to the Board

(a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) A clinic licensed by the board may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(c) The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board.

(e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) Nothing in this section shall limit the ability of a physician and surgeon to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.

4191. Compliance With Department of Public Health Requirements; Who May Dispense Drugs

(a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Duties of Professional Director; Providing Information to Board

(a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is

responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete a Surgical Clinic Self-Assessment Form as determined by the board as a means to promote compliance through self-examination and education. The self-assessment shall assess the clinic’s compliance with current laws and regulations and include information on compounding practices as specified on the most recent version of the Surgical Clinic Self-Assessment Form approved by the board and posted on its internet website. The professional director of the clinic and consulting pharmacist shall certify on the final page of the Surgical Clinic Self-Assessment Form that they have read, reviewed, and completed self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the board. The completed form shall be signed under penalty of perjury, kept on file in the clinic for three years, and made available to the board or its designee, upon request.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in their capacity as medical director or a dentist or podiatrist acting in their capacity as a

director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

4193. Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale

No clinic holding a license pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code). No clinic holding a license pursuant to this article shall offer drugs for sale or shall charge or bill for professional services for the dispensing or administering of drugs.

4194. Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

No Schedule II controlled substance shall be dispensed in the clinic. This limitation does not prohibit a physician from dispensing a Schedule II drug to the extent permitted by subdivision (b) of Section 11158 of the Health and Safety Code and all other provisions of law, nor does it prevent the lawful administration of Schedule II drugs on the premises of the clinic.

4195. Inspection Authorized

The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law.

Article 15.
Veterinary Food-Animal Drug Retailers

4196. License Required: Temporary Licenses; Persons Authorized in Storage Area; Other Requirements; Board Approval of Designated Representative-in-Charge

(a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) 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 fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each

renewal, each veterinary food-animal drug retailer 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 veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) Every veterinary food-animal drug retailer 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 who ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist 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 veterinary food-animal drug retailer 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.

(f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

4197. Minimum Standards: Security; Sanitation; Board Regulations; Waivers

(a) The following minimum standards shall apply to all veterinary food-animal drug retailers licensed by the board:

(1) Each retailer shall store veterinary food-animal drugs in a secure, lockable area.

(2) Each retailer shall maintain on the premises fixtures and equipment in a clean and orderly condition. The premises shall be dry, well-ventilated, and have adequate lighting.

(b) The board may, by regulation, impose any other minimum standards pertaining to the acquisition, storage, and maintenance of veterinary food-animal drugs, or other goods, or to the maintenance or condition of the licensed premises of any veterinary food-animal drug retailer as the board determines are reasonably necessary.

(c) When, in the opinion of the board, a high standard of patient safety consistent with good animal safety and care in the case of an animal patient can be provided by the licensure of a veterinary food-animal drug retailer that does not meet all of the requirements for licensure as a veterinary food-animal drug retailer, the board may waive any licensing requirements.

4198. Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

(a) Each veterinary food-animal drug retailer shall have written policies and procedures related to the handling and dispensing of veterinary food-animal drugs by veterinary food-animal drug retailers. These written policies and procedures shall include, but not be limited to, the following:

(1) Training of staff.

(2) Cleaning, storage, and maintenance of veterinary food-animal drugs and equipment.

(3) Recordkeeping requirements.

(4) Storage and security requirements.

(5) Quality assurance.

(b) Each retailer shall prepare and maintain records of training and demonstrated competence for each individual employed or retained by the retailer. These records shall be maintained for three years from and after the last date of employment.

(c) Each retailer shall have an ongoing, documented quality assurance program which includes, but is not limited to:

(1) Monitoring personnel performance.

(2) Storage, maintenance, and dispensing of veterinary food-animal drugs.

(d) The records and documents specified in subdivisions (a) and (b) shall be maintained for three years from the date of making.

The records and documents in subdivisions (a), (b), and (c) shall be, at all times during business hours, open to inspection by authorized officers of the law.

(e) To assure compliance with the requirements of this chapter regarding operations of the veterinary food-animal drug retailer, a consulting pharmacist shall visit the veterinary food-animal drug retailer regularly and at least quarterly. The consulting pharmacist shall be retained either on a volunteer or paid basis to review, approve, and revise the policies and procedures of the veterinary food-animal drug retailer, and assure compliance with California and federal law regarding the labeling, storage, and dispensing of veterinary food-animal drugs.

The consulting pharmacist shall certify in writing at least twice a year whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter. The most recent of the written certifications shall be submitted with the annual renewal application of a veterinary food-animal drug retailer license.

4199. Labeling Requirements; Maintaining Prescription Records

(a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to this chapter is subject to the labeling requirements of Sections 4076 and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

Article 16. Applications

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed a version of the California Practice Standards and Jurisprudence Examination for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure and the applicant meets either of the following requirements:

(A) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and holds an active pharmacist license in another state or territory of the United States.

(B) Has passed the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board

the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

4200.1. Multiple Failures of License Examination; Additional Education Requirements

(a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

4200.2. California Practice Standards and Jurisprudence Examination for Pharmacists; Required Inclusions

When developing the California Practice Standards and Jurisprudence Examination for Pharmacists, the board shall include all of the following:

(a) Examination items to demonstrate the candidate's proficiency in patient communication skills.

(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.

4200.3. Examination Process to be Reviewed Regularly; Required Standards

(a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Professional Examination Services or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection and the department as

part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

4200.4. Retaking National Examination After Failure; Waiting Period

An applicant who fails either the North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists may not retake that examination for at least 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.

4200.5. Retired Licensee: Eligibility; Bar on Practice; Requirement for Restoration to Active Status

(a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. The board shall not issue a retired license to a pharmacist whose license has been revoked.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."

(c) The holder of a retired license shall not be required to renew that license.

(d)(1) The holder of a retired license may request to restore their pharmacist license to active status within three years of issuance of the retired license.

(2) A request made pursuant to paragraph (1) shall be accompanied by the renewal fee established in subdivision (e) of Section 4400 and demonstration that, within the two years preceding the request for restoration, the pharmacist has

successfully completed continuing education consistent with the requirements set forth in subdivision (b) of Section 4231.
(3) If more than three years have elapsed since the issuance of the retired license, in order for the holder of a retired license issued pursuant to this section to restore their license to active status, they shall reapply for licensure as a pharmacist consistent with the provisions of Section 4200.

4201. Application Form: Required Information; Authority Granted by License; Reporting Changes in Beneficial Ownership

(a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein or any person with management or control over the license.

(b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information

required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be

reported to the board within 30 days thereafter upon a form to be furnished by the board.

4202. Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline

(a) The board may issue a pharmacy technician license to an individual if the applicant is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board.

(4) Is certified by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an 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.

(d) The board shall not renew a pharmacy technician license unless the applicant submits proof satisfactory to the board that the applicant has successfully completed at least one hour of participation in a cultural competency course, as defined in Section 4231, during the two years preceding the application for renewal.

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

(f) Once an individual is licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

(g) This section shall become operative on January 1, 2024.

4202.5. Designated Paramedic License; Fee

(a) The board may issue a designated paramedic license to an individual if they hold 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).

(f) This section shall be repealed on January 1, 2025.

4202.5. Designated Paramedic License; Fee

(a) The board may issue a designated paramedic license to an individual if they hold 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) This section shall become operative on January 1, 2025.

4202.6. Denial of Federal Registration to Distribute Controlled Substances

Notwithstanding Section 480, the board may deny an application for licensure under this chapter if any of the following conditions apply:

(a) The applicant has been convicted of a crime or subjected to formal discipline that would be grounds for denial of a federal registration to distribute controlled substances.

(b) The applicant has been convicted of a crime involving fraud in violation of state or federal laws related to health care.

(c) The applicant has been convicted of a crime involving financial identify theft.

4203. Non-Profit Clinic License Application: Form; Investigation

(a) Each application for a license under Section 4180 shall be made on a form furnished by the board. The form of application for a license under Section 4180 shall contain the name and address of the applicant, whether the applicant is licensed as a primary care clinic as defined in this code, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.

(b) Upon the filing of the application and payment of the fee prescribed in subdivision (s) of Section 4400, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a permit is made qualify for a license. The board shall also determine

whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license. The board shall not, however, investigate any matters connected with the operation of a premises, including operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made do not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under this article, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4180. The license shall be renewed annually on or before December 31 of each year upon payment of the renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable.

4203.5. Clinic Application

(a) Notwithstanding any other law, when a clinic applicant submits either type of application described in subdivision (b), the board shall issue a license or incorporate the reported changes, as appropriate, within 30 days of receipt of a completed application and payment of any prescribed fees.

(b) This section applies to the following types of applications:

(1) A new clinic license application filed under Section 4180.

(2) Applications to report changes to an existing site licensed under Section 4180, including, but not limited to, changes in professional director, clinic administrator, corporate officers, change of location, or change of address.

(c) This section shall not be construed to limit the board's authority to conduct an investigation to determine whether applicants and the premises for which an application is made qualify for a license.

4203.6. Correctional Clinics: License Application

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

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

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

4204. Surgical Clinic Application: Form; Investigation

(a) Each application for a license under Section 4190 shall be made on a form furnished by the board. The form of application for a license under this article shall contain the name and address of the applicant, whether the applicant is licensed, the type of services the facility will offer, the name of its professional

director, the name of its administrator, and the name of its consulting pharmacist.

(b) Each initial application shall contain a statement from a consulting pharmacist certifying that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of health and safety of the public. Upon the filing of the application and the payment of a fee in subdivision (s) of Section 4400, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for a license. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license. The board shall not however, investigate any matters connected with the operation of a premises, including operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made do not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under Section 4190, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4190. The license shall be renewed annually upon payment of a renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable. As part of the renewal process the consulting pharmacist shall certify compliance with the quarterly inspections as required in Section 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in Section 4192 shall also be provided to the board.

4205. Sale or Dispensing of Hypodermic Syringes and Needles: When Separate License Required; Form and Content of Application; Renewability; Discipline

(a) A license issued pursuant to Section 4110, 4120, 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use.

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of Article 9 (commencing with Section 4140) of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

4207. Investigation by Board

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

4208. Intern Pharmacist License

(a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license shall be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the

board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) A person who has not completed the experience requirements necessary to be eligible for the licensure examination may have his or her intern license extended for a period of up to two years at the discretion of the board if he or she is able to demonstrate his or her inability to exercise the privileges of the intern license during the initial license period.

4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice experience before applying for the pharmacist licensure examination.

(2) This pharmacy practice experience shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board.

(3) This pharmacy practice experience shall include 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and shall include pharmacy practice experience in both a community and institutional pharmacy practice setting.

(b) An intern pharmacist shall submit proof of his or her pharmacy practice experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision the experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Pharmacy practice experience earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of pharmacy practice experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a

pharmacist and has pharmacy practice experience in both a community and institutional pharmacy practice setting. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(d) An applicant for the examination who has graduated after January 1, 2016, from an ACPE accredited college of pharmacy or school of pharmacy recognized by the board shall be deemed to have satisfied the pharmacy practice experience requirements specified in subdivisions (a) and (b).

4210. Advanced Pharmacist Practitioner License

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

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

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

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

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

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

(B) For purposes of this paragraph, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy this paragraph.

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

(4) Pay the applicable fee to the board.

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

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

(d) This section shall become operative on January 1, 2025.

4211. Advanced Pharmacist Practitioner; License Renewal; Placed on Inactive Status by Board

(a) An applicant for renewal of an advanced pharmacist practitioner recognition shall maintain a current and active pharmacist license, and shall submit all of the following as part of the renewal:

(1) Application and payment of the renewal fees.

(2) (A) Proof satisfactory to the board that the licensee has completed 10 hours of continuing education pursuant to Section 4233.

(B) The 10 hours shall be in addition to the continuing education requirements necessary for a pharmacist license renewal pursuant to Section 4231.

(C) An advanced pharmacist practitioner shall retain documentation of completion of continuing education for four years.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an advanced pharmacist practitioner recognition.

(c) The board may issue an inactive advanced pharmacist practitioner recognition under any of the following conditions:

(1) The pharmacist's license becomes inactive.

(2) The advanced pharmacist practitioner fails to provide documentation of the completion of the required continuing education.

(3) As part of an investigation or audit conducted by the board, the advanced pharmacist practitioner fails to provide

documentation substantiating the completion of continuing education.

(d) The board shall reactivate an inactive advanced pharmacist practitioner recognition only if the advanced pharmacist practitioner pays the required renewal fees pursuant to Section 4210, submits satisfactory proof to the board of completion of the continuing education requirements under Section 4233, and meets all renewal requirements in this section.

Article 17. Continuing Education

4231. Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

(a) For purposes of this section, "cultural competency course" means a cultural competency and humility course that meets the following criteria:

(1) The course focuses on patients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, or queer, or who question their sexual orientation or gender identity and expression.

(2) The course is approved from an accreditation agency approved by the board.

(3) The course covers recognized health disparities faced by Black, Indigenous, and people of color.

(4) The course contains elements demonstrating how sexual identity is directly impacted through intersectionality.

(b) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that the applicant has successfully completed 30 hours of approved courses of continuing pharmacy education, including at least one hour of participation in a cultural competency course, during the two years preceding the application for renewal.

(c) Notwithstanding subdivision (b), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(d) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

(e) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (b), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

(f) This section shall become operative on January 1, 2024.

4232. Content of Courses

(a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology,

and any other subject matter as represented in curricula of accredited colleges of pharmacy.

4232.5. Continuing Education Requirement for Prescribing Schedule II Controlled Substances

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

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

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

4233. Advanced Pharmacist Practitioner; Continuing Education Requirement

A pharmacist who is recognized as an advanced pharmacist practitioner shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

4234. Exceptions: Emergencies; Hardship

The board may, in accordance with the intent of this article, make exceptions from the requirements of this article in emergency or hardship cases.

Article 18. Poisons

4240. California Hazardous Substances Act; Application of Act

(a) The California Hazardous Substances Act, Chapter 4 (commencing with Section 108100) of Part 3 of Division 104 of the Health and Safety Code, applies to pharmacies and pharmacists and any other person or place subject to the jurisdiction of the board.

(b) The board may enforce that act when necessary for the protection of the health and safety of the public if prior

regulatory notice is given in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). Board enforcement shall focus on those hazardous substances that relate significantly to or overlap the practice of pharmacy.

(c) "Poison" as used in this chapter refers to a category of hazardous substances defined in Section 108125 of the Health and Safety Code. The board may by regulation make the category more specific.

Article 19. Disciplinary Proceedings

4300. Revocation and Suspension: Authority; Conditions; Issuance of Probationary License; Application of Administrative Procedure Act; Judicial Review

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

4300.1. Board Authority to Render a Decision on a License

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

4301. Obtaining License by Fraud or Misrepresentation; Unprofessional Conduct

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 a person with substance use disorder.

(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 Section 256b(a)(4) 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” has the same meaning given the term in Section 1418 of the Health and Safety Code.

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

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

(v) Actions or conduct that would subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgment, including creating or allowing conditions that may interfere with a pharmacist’s ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.

(w) Actions or conduct that would subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgment, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.

(x) Actions or conduct that would subvert the efforts of a pharmacist intern or a pharmacy technician to comply with laws or regulations.

(y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless those guarantees are required by law or to meet contractual requirements. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.

4301.1. Investigation Priority – Greatest Threat of Patient Harm

In order to ensure that the board's resources are maximized for the protection of the public health and safety, the board shall prioritize its investigative and prosecutorial resources to ensure that pharmacists representing the greatest threat of patient harm are identified and disciplined expeditiously.

4301.5. Pharmacist License; Out-of-State Suspension or Revocation to Apply to California License

(a) If a pharmacist possesses a license or is otherwise authorized to practice pharmacy in any other state or by an agency of the federal government, and that license or authority is suspended or revoked, the pharmacist's license shall be suspended automatically for the duration of the suspension or revocation, unless terminated or rescinded as provided in subdivision (c). The board shall notify the pharmacist of the license suspension and of his or her right to have the issue of penalty heard as provided in this section.

(b) Upon its own motion or for good cause shown, the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the pharmacy profession.

(c) The issue of penalty shall be heard by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law judge, or by the board sitting with an administrative law judge, at the board's discretion. A pharmacist may request a hearing on the penalty and that hearing shall be held within 90 days from the date of the request. If the order suspending or revoking the pharmacist's license or authority to practice pharmacy is overturned on appeal, any discipline

ordered pursuant to this section shall automatically cease. Upon the showing to the administrative law judge, board, or committee of the board by the pharmacist that the out-of-state action is not a basis for discipline in California, the suspension shall be rescinded.

If an accusation for permanent discipline is not filed within 90 days of the suspension imposed pursuant to this section, the suspension shall automatically terminate.

(d) The record of the proceedings that resulted in the suspension or revocation of the pharmacist's license or authority to practice pharmacy, including a transcript of the testimony therein, may be received in evidence.

(e) If a summary suspension has been issued pursuant to this section, the pharmacist may request that the hearing on the penalty conducted pursuant to subdivision (c) be held at the same time as a hearing on the accusation.

4302. Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest, or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

4303. Nonresident Pharmacy: Grounds for Discipline

(a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of

admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy.

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

4303.1. Outsourcing Facility – License Canceled, Revoked or Suspended by Operation of Law

If the federal Food and Drug Administration (FDA) cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant to Section 4129.2 shall be immediately canceled, revoked, or suspended by operation of law.

4304. Nonresident Wholesaler; Authority to Discipline

The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code.

4305. Disciplinary Grounds: Failure of Pharmacy or Pharmacist to Notify Board of Termination of Pharmacist-in-Charge; Continuing to Operate Without Pharmacist

(a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act as the pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in Sections 4101 and 4113 shall constitute grounds for disciplinary action.

(b) Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

4305.5. Disciplinary Grounds: Failure of Wholesaler, Veterinary Food-Animal Drug Retailer or Third-Party Logistics Provider to Notify Board of Termination of Designated Representative-in-Charge or Responsible Manager; Continuing to Operate Without Designated Representative-in-Charge or Responsible Manager

(a) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge or responsible manager. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, that willfully fails to notify the board of the termination of employment of the designated representative-in-charge or responsible manager at its licensed place of business, and that continues to operate the place of business in the absence of the designated representative-in-charge or responsible manager for that place of business shall be subject to summary suspension or revocation of its license as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer at that place of business.

(c) A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, or a responsible manager of a third-party logistics provider, who terminates his or her employment at the licensed place of business, shall notify the board within 30 days of the termination of employment. Failure

to notify the board within the 30-day period shall constitute grounds for disciplinary action.

4306. Violation of Professional Corporation Act as Unprofessional Conduct

It shall constitute unprofessional conduct and a violation of this chapter for any person licensed under this chapter to violate, attempt to violate, directly or indirectly, or assist in or abet the violation of, or conspire to violate, any provision or term of this article, the Moscone-Knox Professional Corporation Act, or any regulations duly adopted under those laws.

4306.5. Acts or Omissions by Pharmacist: Unprofessional Conduct

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

4306.6. Mitigating Factors for Pharmacist-in-Charge Reporting Violations of Others

If the board disciplines a pharmacist-in-charge for the violation of a state or federal law or regulation committed by another person and the pharmacist-in-charge reported to the board that violation or suspected violation, the board shall use the report as a mitigating factor if all of the following conditions are met:

(a) The pharmacist-in-charge did not engage, either directly or indirectly, in any conduct that violated any state or federal law or regulation pertaining to the practice of pharmacy.

(b) The pharmacist-in-charge did not permit, encourage, approve of, either tacitly or implicitly or through willful ignorance, any conduct committed by another person that violated state or federal law or regulation pertaining to the practice of pharmacy.

(c) The pharmacist-in-charge reported the violation, or suspected violation, of any state or federal law or regulation pertaining to the practice of pharmacy to the board as soon as reasonably possible following the discovery of the violation.

(d) The pharmacist-in-charge took all actions reasonably necessary to stop and remedy the violation, or suspected violation, of any state or federal law or regulation pertaining to the practice of pharmacy as soon as reasonably possible following the discovery of the violation.

4307. Individuals with Denied, Revoked, Suspended, etc. Licenses Prohibited From Pharmacy Ownership or Association with Board Licensed Entities

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator,

owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

4308. Prohibited Association: Notification of Affected Licensees Known to Board

Whenever a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position of management or control of a licensee as provided by Section 4307, the board shall, in each case where it has that information, notify in writing each licensee for whom the person is a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of the prohibition. The board shall send the notification to the licensee's address of record. The licensee shall have 30 days from the date that the notice is sent to remove and replace the prohibited person and, where appropriate, file a change of permit to reflect that change.

4309. Petition for Reinstatement, etc. of Disciplined License: Time for Filing; Contents; Investigation; Hearing; Factors to be Considered; Effect of Ongoing Criminal Sentence, Accusation, or Petition to Revoke Probation

(a) A person whose license has been revoked or suspended or who has been placed on probation may petition the board for reinstatement or modification of penalty, including modification or termination of probation, after not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

(1) At least three years for reinstatement of a revoked license.

(2) At least two years for early termination of probation of three years or more.

(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

(b) The petition shall state any facts required by the board, and the petition shall be accompanied by two or more verified recommendations from holders of licenses issued by the board to which the petition is addressed, and two or more recommendations from citizens, each having personal knowledge of the disciplinary penalty imposed by the board and the

activities of the petitioner since the disciplinary penalty was imposed.

(c) The petition may be heard by the board sitting with an administrative law judge, or a committee of the board sitting with an administrative law judge, or the board may assign the petition to an administrative law judge. Where the petition is heard by a committee of the board sitting with an administrative law judge or by an administrative law judge sitting alone, the decision shall be subject to review by the board pursuant to Section 11517 of the Government Code.

(d) In considering reinstatement or modification of penalty, the board, committee of the board, or the administrative law judge hearing the petition may consider factors including, but not limited to, all of the following:

(1) All the activities of the petitioner since the disciplinary action was taken.

(2) The offense for which the petitioner was disciplined.

(3) The petitioner's activities during the time the license was in good standing.

(4) The petitioner's documented rehabilitative efforts.

(5) The petitioner's general reputation for truth and professional ability.

(e) The hearing may be continued from time to time as the board, committee of the board, or the administrative law judge designated in Section 11371 of the Government Code finds necessary.

(f) The board, committee of the board, or administrative law judge may impose necessary terms and conditions on the licensee in reinstating the license.

(g) No petition under this section shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole. No petition shall be considered while there is an accusation or petition to revoke probation pending against the person. The board may deny without a hearing or argument any petition filed pursuant to this section within a period of two

years from the effective date of the prior decision following a hearing under this section.

(h) Nothing in this section shall be deemed to amend or otherwise change the effect or application of Sections 822 and 823.

(i) The board may investigate any and all matters pertaining to the petition and documents submitted with or in connection with the application.

4310. Notice of Denial of Application: Petition for Licensure; Application of Administrative Procedure Act

Immediately upon the denial of any application for a license the board shall notify the applicant in writing. Within 10 days after the board mails the notice, the applicant may present his or her written petition for a license to the board. Upon receipt by the board of the written petition, proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

4311. Suspension of License for Felony Conviction: Automatic Suspension; Summary Suspension; Other Suspensions; Applicable Proceedings

(a) Any license issued by the board, or the holder thereof, shall be suspended automatically during any time that the person is incarcerated after conviction of a felony, regardless of whether the conviction has been appealed. The board, immediately upon receipt of a certified copy of a record of a criminal conviction, shall determine whether the person has been automatically suspended by virtue of incarceration pursuant to a felony conviction and, if so, the duration of that suspension. The board shall notify the person so suspended of the suspension and that the person has a right to request a hearing, solely as to whether he or she is incarcerated pursuant to a felony conviction, in writing at that person's address of record with the board and at the facility in which the person is incarcerated.

(b) In addition to any suspension under subdivision (a), the board shall summarily suspend any license issued by the board

where a conviction of the holder of the license meets the requirements of paragraphs (1) and (2).

(1) A felony that was either of the following:

(A) Committed in the course of a business or practice for which the board issues a license.

(B) Committed in a manner that a client, customer, or patient of the licensee was a victim.

(2) Where an element of the offense involves either of the following:

(A) The specific intent to deceive, defraud, steal, or make a false statement.

(B) The illegal sale or possession for sale of or trafficking in any controlled substance.

(3) The suspension shall continue until the time for appeal has elapsed, if no appeal is taken, or until the judgment of conviction has been affirmed on appeal or has otherwise become final, and until further order of the board.

(4) The board shall immediately send notice in writing of the suspension to the licensee, or the holder of any other board-issued license, at his or her address of record and, if incarcerated at the time, at the facility in which the person is incarcerated. The notice shall include notification of that person's right to elect to have the issue of penalty heard as provided in paragraph (2) of subdivision (d), and of the right to request a hearing to contest the summary suspension. Any request for a hearing under this paragraph must be received by the board within 15 days following receipt of the notice provided for by this paragraph.

(5) The hearing shall be before an administrative law judge, a committee of the board sitting with an administrative law judge, or the board sitting with an administrative law judge, at the board's discretion, and shall be subject to review by the board, at its discretion. The hearing shall be limited to (A) whether there has been a felony conviction as stated in the board's notice, and (B) whether the conviction meets the criteria of this subdivision, except where the licensee chooses to proceed as provided by paragraph (2) of subdivision (d), or where the board has also filed and served an accusation as provided in Chapter 5 (commencing

with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of the hearing as required by that chapter; provided that if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case.

(c) In addition to any suspension under subdivision (a), the board shall also suspend any license issued by the board, or the holder thereof, if the board determines that the felony conviction of the holder of the license is substantially related to the qualifications, functions, or duties of the licensee.

(1) Notice of the board's determination shall be sent to the licensee, or the holder thereof, at that person's address of record with the board and, if the person is incarcerated at the time, the facility in which the person is incarcerated. The notice shall advise the person that the license shall be suspended without hearing unless, within 15 days following receipt of the notice, a written request for hearing is delivered to the board.

(2) Upon receipt of a timely request for hearing, a notice of hearing shall be sent to the person at least 10 days before the date scheduled for the hearing. The notice of hearing shall include notification of that person's right to elect to have the issue of penalty heard as provided in paragraph (2) of subdivision (d).

(3) The hearing to determine whether a felony conviction is substantially related for purposes of an interim suspension under this subdivision shall be separate from any hearing on an accusation under the Administrative Procedure Act, except where the licensee elects to proceed under paragraph (2) of subdivision (d), or where the board has filed and served an accusation as provided by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of hearing as required by that chapter. The hearing on whether the felony conviction is substantially related shall be heard either by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law

judge, or by the board sitting with an administrative law judge, at the board's discretion, and shall be subject to review by the board, at its discretion. However, if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case. Except where a person proceeds under paragraph (2) of subdivision (d), or the board proceeds with an accusation at the same time, any suspension imposed under this subdivision shall continue until an accusation is filed under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and a final decision is rendered by the board.

(4) A conviction of any crime referred to in Section 4301, or for violation of Section 187, 261, or 288 of the Penal Code, shall be conclusively presumed to be substantially related to the qualifications, functions, or duties of a licensee of the board. Upon its own motion or for good cause shown the board may decline to impose a suspension under this subdivision or may set aside a suspension previously imposed when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the practice of pharmacy and the handling of dangerous drugs and devices.

(d) (1) Discipline may be ordered in accordance with Section 4300 or an application denied when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or 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, setting aside the verdict of guilty, or dismissing the accusation, complaint, information, or indictment.

(2) The issue of penalty shall be heard by an administrative law judge sitting alone or with a committee of the board or with the board itself, at the board's discretion, and any decision shall be subject to review by the board, at its discretion. The hearing shall not be held until the judgment of conviction has become

final or, irrespective of a subsequent order under Section 1203.4 of the Penal Code, an order granting probation has been made suspending the imposition of sentence, provided that a licensee may, at his or her option, elect to have the issue of penalty decided before those time periods have elapsed. Where the licensee so elects, the issue of penalty shall be heard in the manner described in this section at the hearing to determine whether the conviction was substantially related to the qualifications, functions, or duties of the licensee. If the conviction of a licensee who has made this election is overturned on appeal, any discipline ordered pursuant to this section shall automatically cease. Nothing in this subdivision shall prohibit the board from pursuing disciplinary action based on any cause, including the facts underlying the conviction, other than the overturned conviction.

(3) The record of the proceedings resulting in the criminal conviction, including a transcript of any testimony taken in connection with the proceeding, may be received in evidence in any administrative proceeding to the extent the testimony would otherwise be admissible under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. A certified copy of the criminal conviction shall be conclusive proof of the fact of the conviction.

(e) Other provisions of this chapter setting forth procedures for the suspension or revocation of a license issued by the board shall not apply to proceedings conducted pursuant to this section, except as specifically provided in this section.

(f) For purposes of this section, a crime is a felony if it is specifically declared to be so or is made a felony by subdivision (a) of Section 17 of the Penal Code, unless it is charged as a misdemeanor pursuant to paragraph (4) or (5) of subdivision (b) of Section 17 of the Penal Code, irrespective of whether in a particular case the crime may be considered a misdemeanor as a result of postconviction proceedings. For purposes of this section, a felony also includes a conviction under federal law, or the law of any other state of the United States, of the District of Columbia, or of any territory or possession of the United States.

A conviction includes a plea or verdict of guilty or a conviction following a plea of nolo contendere.

(g) The board may delegate the authority to issue a suspension under subdivision (a) or (b) or a notice of suspension under subdivision (c) to the executive officer of the board.

4312. Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock

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

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

(c) If a licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in

the county in which the facility licensed by the board is located, authorizing the board to enter the facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the facility.

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

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

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

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

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

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

4313. Evidence of Rehabilitation; Priority of Public Protection

In determining whether to grant an application for licensure or whether to discipline or reinstate a license, the board shall give consideration to evidence of rehabilitation. However, public protection shall take priority over rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence.

4314. Orders of Abatement

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

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

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

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section
56.36 of the Civil Code, and the regulations adopted pursuant to those sections.
(e) The issuance of a citation pursuant to subdivision (b) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

4315. Letter of Admonishment

(a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733, for failure to comply with this chapter or regulations adopted pursuant to this chapter, or for failure to comply with Division 116 (commencing with Section 150200) of the Health and Safety Code, directing the licensee to come into compliance.

(b) The executive officer, or his or her designee, may issue a letter of admonishment to an applicant for licensure who has committed any violation of law that the board deems, in its discretion, does not merit the denial of a license or require probationary status under Section 4300. The letter of admonishment may be issued concurrently with a license.

(c) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(d) The letter of admonishment shall inform the licensee or applicant that within 30 days of service of the order of admonishment the licensee or applicant may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or applicant or his or her legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized

representative of the licensee or applicant may accompany the licensee or applicant to the office conference.

(B) Prior to or at the office conference, the licensee or applicant may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), or Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send the board's written decision by certified mail to the licensee's or applicant's address of record. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and, if required, submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(e) The letter of admonishment shall be served upon the licensee or applicant personally or by certified mail at his or her address of record with the board. If the licensee or applicant is

served by certified mail, service shall be effective upon deposit in the United States mail.

(f) The licensee or applicant shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(g) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067, or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to this article.

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

4316. Board Authorized to Issue Cease and Desist Orders

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

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

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice

president of the board may conduct the hearing permitted by this subdivision. The owner or person in possession or control of the facility may seek review of the decision of the president of the board pursuant to Section 1094.5 of the Code of Civil Procedure.

4316.5. Enforcement
Notwithstanding any other law, the board may assess administrative fines and issue orders of abatement to any unlicensed entity who engages in any action that requires licensure under the jurisdiction of the board, not to exceed five thousand dollars ($5,000) for each occurrence pursuant to a citation issued by the board.

4317. Action Against Chain Community Pharmacy for Violating Prohibition on Quotas
The board may take an enforcement action against a chain community pharmacy, as defined in subdivision (c) of Section 4001, that violates Section 4113.7 unless, by clear and convincing evidence, the chain community pharmacy demonstrates that the violation was contrary to its policy.

4317.5. Fines for Repeated Violations by Chain Pharmacies
(a) The board may bring an action for fines for repeated violations of materially similar provisions of this chapter within five years by three or more pharmacies operating under common ownership or management within a chain community pharmacy, a third or subsequent violation, which may be punished by an administrative fine not to exceed one hundred thousand dollars ($100,000) per violation.
(b) The board may bring an action against a chain community pharmacy operating under common ownership or management for fines not to exceed one hundred fifty thousand dollars ($150,000) for any violation of this chapter demonstrated to be the result of a written policy or that was expressly encouraged by any owner or manager.

(c) The board shall not bring an action for fines pursuant to subdivision (a) until at least six months have elapsed from the date the board determines that a violation has occurred unless the violation giving rise to the action resulted in actual harm to any consumer or serious potential harm to the public.
(d) In an action brought by the board pursuant to subdivision (a), it shall be a defense for any pharmacy to establish either of the following:
(1) That the violation was contrary to a written policy that was communicated by any owner or manager to all employees of the pharmacies where the violation occurred, and that the pharmacy has complied with the policy.
(2) That, within six months after the violation, the common owner or manager corrected all unlawful policies, communicated the change in policy or policies in writing to all pharmacies under its ownership or management, and provided proof of abatement of the violation to the board, so long as the violation did not result in actual harm to any consumer or serious potential harm to the public.
(e) In determining the amount of the fine sought in an action brought pursuant to this section, the board shall consider relevant mitigating and aggravating factors, including, but not limited to, the good faith of the licensee, the communication of written changes to unlawful policies, the gravity of the violation, the potential harm to patients, whether the violation affects the professional judgment or independence of pharmacists and pharmacy technicians, and the history of previous violations by the common owner or manager.
(f) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.
(g) For purposes of this section, “chain community pharmacy” shall have the same meaning as defined in Section 4001.
(h) The fines in subdivisions (a) and (b) shall be imposed in accordance with Section 4314.

4317.6. Fines for Mail Order Pharmacy

(a) For the purposes of this section, “mail order pharmacy” is defined as a nonresident pharmacy that dispenses medications and ships them to patients via the postal service or other mail delivery method.

(b) The board may bring an action for fines for repeated violations of materially similar provisions of this chapter within five years for a single mail order pharmacy, or multiple mail order pharmacies operating under common ownership or management for a third or subsequent violation, which may be punished by an administrative fine not to exceed one hundred thousand dollars ($100,000) per violation.

(c) The board shall not bring an action for fines pursuant to subdivision (b) until at least six months have elapsed from the date the board determines that a violation has occurred unless the violation giving rise to the action resulted in actual harm to any consumer or serious potential harm to the public.

(d) In determining the amount of the fine sought in an action brought pursuant to this section, the board shall consider relevant mitigating and aggregating factors, including, but not limited to, the good faith of the licensee, the communication of written changes to unlawful policies, the gravity of the violation, the potential harm to a patient, whether the violation affects the professional judgment or independence of pharmacists, and the history of previous violations by the mail order pharmacy, or in the case of multiple mail order pharmacies operating under common ownership or management, the history of the previous violations by the common ownership or control.

(e) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.

(f) The fines in subdivision (b) shall be imposed in accordance with Section 4314.

4318. Reproductive Privacy

(a) Notwithstanding any other state law, and consistent with Sections 1 and 1.1 of Article I of the California Constitution, an individual or state or local officer shall not commence a criminal, civil, professional discipline, or licensing action concerning the manufacture, transport, distribution, delivery, receipt, acquisition, sale, possession, furnishment, dispensation, repackaging, or storage of brand name or generic mifepristone or any drug used for medication abortion that is lawful under the laws of the state.

(b) The board shall not suspend a license, revoke a license, or otherwise take disciplinary action against a licensee solely on the basis that the licensee manufactured, transported, distributed, delivered, received, acquired, sold, possessed, furnished, dispensed, repackaged, or stored brand name or generic mifepristone or any drug used for medication abortion that is lawful under the laws of the state.

(c) The board shall not deny an application for licensure, or suspend a license, revoke a license, or otherwise impose discipline upon a licensee solely because the licensee is licensed in another state and was convicted or disciplined in that state solely for an activity related to brand name or generic mifepristone or any drug used for medication abortion that, if performed in this state, would not be grounds for denial, suspension, revocation, or other discipline.

Article 20. Prohibitions and Offenses

4320. Penalties for Violation of Pharmacy Law: Actions Authorized; Who May File Actions

(a) The penalties prescribed in this chapter may be recovered in any court having jurisdiction, by a civil action instituted by the board in the name of the State of California, or by criminal prosecution upon complaint being made.

(b) The district attorney of the county wherein violations of this chapter occur shall conduct all felony prosecutions at the request of the board. The district attorney of the county or city attorney

of the city wherein violations of this chapter occur shall conduct all other actions and prosecutions at the request of the board.

4321. Penalties: Misdemeanors; Infractions

(a) Any person who knowingly violates any of the provisions of this chapter, when no other penalty is provided, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine of not less than two hundred dollars ($200), and not more than two thousand dollars ($2,000), or by imprisonment of not less than 30 days nor exceeding six months, or by both that fine and imprisonment.

(b) In all other instances, any person who violates any of the provisions of this chapter, when no other penalty is provided, is guilty of an infraction, and upon conviction thereof may be punished by a fine not to exceed one thousand dollars ($1,000).

4322. Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties

Any person who attempts to secure or secures licensure for himself or herself or any other person under this chapter by making or causing to be made any false representations, or who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars ($5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment.

4323. Misdemeanor; False Representation of Self as a Physician, Agent of Physician, etc. to Obtain Drug

Every person who, in order to obtain any drug, falsely represents himself or herself to be a physician or other person who can lawfully prescribe the drug, or falsely represents that he or she is acting on behalf of a person who can lawfully prescribe the drug, in a telephone or electronic communication with a pharmacist, shall be punished by imprisonment in the county jail for not more than one year.

4324. Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in the county jail for not more than one year.

4325. Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank

(a) No person other than a physician, dentist, podiatrist, veterinarian, pharmacist, or other person authorized by law to dispense, administer, or prescribe controlled substances, or the person's agent acting under authorization by the person to print prescription blanks, and acting in the regular practice of the person's profession, shall knowingly and willfully manufacture, copy, reproduce, or possess, or cause to be manufactured, copied, reproduced, or possessed, any prescription blank that purports to bear the name, address, and federal registry or other identifying information of a physician, dentist, podiatrist, veterinarian, or other person authorized by law to dispense, administer, or prescribe controlled substances.

(b) Every person who violates this section shall be guilty of a misdemeanor.

4327. Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages

Any person who, while on duty, sells, dispenses or compounds any drug while under the influence of any dangerous drug or alcoholic beverages shall be guilty of a misdemeanor.

4328. Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-Pharmacist

Except as otherwise provided in this chapter, any person who permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor.

4329. Misdemeanor: Non-Pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs

Any non-pharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

4330. Misdemeanor: Non-Pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist-in-Charge

(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) Any pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

4331. Misdemeanor: Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Designated Representative in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Designated Representative

(a) A person 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.

4332. Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Reports

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

4333. Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records is Misdemeanor

(a) All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

(b) Any person who willfully fails to comply with subdivision (a) is guilty of a misdemeanor, and upon conviction thereof, shall be punished by a fine not exceeding two hundred dollars ($200). Any person convicted of a second or subsequent offense shall be punished by a fine of not less than two hundred dollars ($200) and not more than four hundred dollars ($400).

(c) (1) Notwithstanding subdivisions (a) and (b), the board may, upon written request, grant a waiver of the requirement that the records described in subdivisions (a) and (b) be maintained on the licensed premises or, in the event the pharmacy discontinues business, that the records be maintained in a board licensed facility. A person who maintains records in compliance with that waiver is not subject to the penalties set forth in subdivision (b).

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

4335. Knowingly Failing to Arrange for Disposition of Stock of Closed or Discontinued Business: Misdemeanor

Any person who knowingly violates subdivision (b) of Section 4312 is guilty of a misdemeanor.

4336. Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

(a) Every person who knowingly or willfully violates Section 4055, 4059, 4060, 4061, 4062, 4063, 4064, 4065, 4077, 4080, 4081, 4083, or 4332 with respect to dangerous drugs by use of a minor as an agent is guilty of a felony.

(b) Nothing contained in this section shall apply to a pharmacist furnishing dangerous drugs pursuant to a prescription.

4337. Distribution of Fines Collected

Except as otherwise specified, all fines collected for violations of this chapter shall be paid as follows: one-half into the State Treasury to the credit of the Contingent Fund of the Board of Pharmacy of the State of California and one-half to the treasurer of the jurisdiction in which the misdemeanor is prosecuted, to be deposited in the same fund as fines for other misdemeanors occurring in that jurisdiction are deposited.

4338. Additional Fines May be Assessed

In addition to any fine assessed under Section 4321, the judge may assess a fine not to exceed seventy dollars ($70) against any person who violates Section 4140 or 4142, with the proceeds of this fine to be used in accordance with Section 1463.23 of the Penal Code. The court shall, however, take into consideration the defendant's ability to pay and no defendant shall be denied probation because of his or her inability to pay the fine permitted under this section.

4339. Board Action to Enjoin Violation of Pharmacy Law; Exception for Certain Drugs and Devices

(a) The board may bring an action to enjoin the violation of any provision of this chapter in any superior court in and for the county in which the violation has occurred. Any action shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the board shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or irreparable damage or loss. The action shall be brought in the name of the people of the State of California.

(b) Nothing in this section shall permit the bringing of any action with respect to any drug or product not subject to Section 4022 that is packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(c) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.

4340. Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

It is unlawful for any nonresident pharmacy that is not registered pursuant to Section 4112 or for any person who is a resident of this state to advertise the pharmacy services of any pharmacy, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

4341. Advertisement of Prescription Drugs or Devices

Notwithstanding any other provision of law, prescription drugs or devices may be advertised if the advertisement conforms with the requirements of Section 651.

4342. Actions by Board to Prevent Sales of Preparations or Drugs Lacking Quality of Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336.

4343. Buildings: Prohibition Against the Use of Certain Signs Unless Licensed Pharmacy Within

No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110.

Article 21. Pharmacists Recovery Program

4360. Impaired Pharmacists: Legislative Intent

The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

4361. Definitions

(a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

4362. Function of Program: Board Referrals; Voluntary, Confidential Participation

(a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

4364. Criteria for Participation to be Established by Board

(a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4365. Contracting with Employee Assistance Program: Selection

The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.

4366. Function of the Employee Assistance Program

The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:

(a) To evaluate those pharmacists and intern pharmacists who request participation in the program.

(b) To develop a treatment contract with each participant in the pharmacists recovery program.

(c) To monitor the compliance of each participant with their treatment contract.

(d) To prepare reports as required by the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

4369. Board Referrals to Program: Written Information Provided to Licensee; Termination for Non-Compliance; Report to Board of Termination; Authority to Discipline

(a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

4371. Review of Program Activities

(a) The executive officer of the board shall designate a program manager of the pharmacists recovery program. The program manager shall have background experience in dealing with substance abuse issues.

(b) The program manager shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the program manager shall review files of all participants in the pharmacists recovery program.

(c) The program manager shall work with the contractor administering the pharmacists recovery program to evaluate participants in the program according to established guidelines and to develop treatment contracts and evaluate participant progress in the program.

4372. Confidential Records; Exception for Disciplinary Proceeding

All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

4373. Immunity from Civil Liability

No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

Article 22. Unfair Trade Practices

4380. Resale of Preferentially Priced Drugs: Prohibition; Exceptions

(a) The resale, by any person, of drugs acquired at preferentially low prices permitted under federal law only because of the Nonprofit Institutions Act (15 U.S.C. Sec. 13c) is prohibited except in any of the following instances:

(1) When for the person's own use, as defined by the federal courts in Abbott Labs. v. Portland Retail Druggists (425 U.S. 1, 47 L. Ed. 2d 537) and DeModena v. Kaiser Foundation Health Plan, Inc. (743 F. 2d 1388).

(2) When sold to a purchaser also eligible for those prices under the Nonprofit Institutions Act, that controls, is controlled by, or is under common control with, the seller, and that purchases the products for its own use, as defined in paragraph (1).

(3) When sold to a walk-in customer pursuant to a prescription, provided that those sales represent less than 1 percent of the drugs purchased by the seller for its own use in this state.

(b) Nothing in this article prohibits the resale of drugs to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need.

4381. Violation of Article as Unfair Competition; Private Actions Authorized; Triple Damages and Attorneys' Fees; Proof Required

(a) A violation of this article is an act of unfair competition within the meaning of Chapter 5 (commencing with Section 17200) of Part 2 of Division 7, and this article is enforceable as provided in that chapter.

(b) In addition thereto, any person or trade association may bring an action to enjoin and restrain any violation of this article and to recover actual damages, if any.

(c) In an action for injunctive relief under this article, it is not necessary to allege or prove actual damages or the threat thereof, or actual injury or the threat thereof, to the plaintiff. In addition to injunctive relief, the plaintiff in any action shall recover three times the amount of his or her actual damages, if any, as well as three times the actual damages, if any, sustained by any person who has assigned to the plaintiff a claim for damages resulting from a violation of this section. In any action under this article in which judgment is entered against the defendant, the plaintiff shall be awarded reasonable attorneys' fees together with the costs of suit.

(d) In issuing an injunction against a violation under this article, the court may, in its discretion, include any other restraint it deems expedient in order to deter the defendant from and ensure against future violations of this article.

(e) Proof of malice or intent to harm competition is immaterial to sustain a cause of action under this article.

4382. Board May Audit Sales to Walk-In Customers

The board may audit persons for compliance with the limits established in paragraph (3) of subdivision (a) of Section 4380 except that in the case of a facility or pharmacy that predominately serves members of a prepaid group practice health care service plan, those audits may be undertaken solely by the Department of Managed Health Care pursuant to its authority to audit those plans.

Article 23. Revenue and Renewal

4400. Fees

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) (1) The fee for a pharmacy license shall be seven hundred fifty dollars ($750) and may be increased to two thousand dollars ($2,000). The fee for the issuance of a temporary pharmacy permit shall be one thousand six hundred dollars ($1,600) and may be increased to two thousand seven hundred forty dollars ($2,740).

(2) The fee for a nonresident pharmacy license shall be two thousand four hundred twenty-seven dollars ($2,427) and may be increased to three thousand four hundred twenty-four dollars ($3,424). The fee for the issuance of a temporary nonresident pharmacy permit shall be two thousand dollars ($2,000) and may be increased to two thousand four hundred sixty-nine dollars ($2,469).

(b) (1) The fee for a pharmacy license annual renewal shall be one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000).

(2) The fee for a nonresident pharmacy license annual renewal shall be one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000).

(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 one hundred fifteen dollars ($115) and may be increased to two hundred dollars ($200). 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 four hundred fifty dollars ($450) and may be reduced to three hundred sixty dollars ($360).

(f) The fee for a wholesaler or third-party logistics provider license and annual renewal shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be increased to one thousand nine dollars ($1,009).

(g) The fee for a hypodermic license shall be five hundred fifty dollars ($550) and may be increased to seven hundred seventy-five dollars ($775). The fee for a hypodermic license renewal shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be three hundred forty-five dollars ($345) and may be increased to four hundred eighty-five dollars ($485).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be three hundred eighty-eight dollars ($388) and may be increased to five hundred forty-seven dollars ($547).

(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 three hundred forty-five dollars ($345) and may be increased to four hundred eighty-five dollars ($485).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred eighty-eight dollars ($388) and may be increased to five hundred forty-seven dollars ($547).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411).

(2) A temporary license fee shall be seven hundred fifteen dollars ($715) and may be increased to one thousand nine dollars ($1,009).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411).

(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 seventy-five dollars ($175) and may be increased to two hundred forty-five dollars ($245). The fee for transfer of intern hours or verification of licensure to another state shall be one hundred twenty dollars ($120) and may be increased to one hundred sixty-eight dollars ($168).

(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 seventy-five dollars ($75) and may be increased to one hundred dollars ($100).

(o) (1) The fee for processing an application to change information on a premises license record shall be three hundred ninety-five dollars ($395) and may be increased to five hundred fifty-seven dollars ($557).

(2) The fee for processing an application to change a name or correct an address on a premises license record shall be two

hundred six dollars ($206) and may be increased to two hundred eighty-two dollars ($282).

(3) The fee for processing an application to change a pharmacist-in-charge, designated representative-in-charge, or responsible manager on a premises license record shall be two hundred fifty dollars ($250) and may be increased to three hundred fifty-three dollars ($353).

(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 clinic license shall be six hundred twenty dollars ($620) and may be increased to eight hundred seventy-three dollars ($873). The annual fee for renewal of the license shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred twenty dollars ($120) and may be increased to one hundred sixty-five dollars ($165). The fee for renewal of a pharmacy technician license shall be one hundred eighty dollars ($180) and may be reduced to one hundred twenty-five dollars ($125).

(s) The fee for a veterinary food-animal drug retailer license shall be six hundred ten dollars ($610) and may be increased to eight hundred twenty-five dollars ($825). The annual renewal fee for a veterinary food-animal drug retailer license shall be four hundred sixty dollars ($460) and may be increased to five hundred sixty-one dollars ($561). The fee for the temporary license shall be five hundred twenty dollars ($520) and may be increased to seven hundred thirty-two dollars ($732).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be fifty dollars ($50) and may be increased to one hundred dollars ($100).

(u) The fee for issuance of a sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be three thousand eight hundred seventy-five dollars ($3,875) and may be increased to five thousand four hundred sixty-six dollars

($5,466). The fee for a temporary license shall be one thousand sixty-five dollars ($1,065) and may be increased to one thousand five hundred three dollars ($1,503). The annual renewal fee of the license shall be four thousand eighty-five dollars ($4,085) and may be increased to five thousand seven hundred sixty-two dollars ($5,762).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be eight thousand five hundred dollars ($8,500) and may be increased to sixteen thousand five hundred two dollars ($16,502). The annual renewal of the license shall be eight thousand five hundred dollars ($8,500) and may be increased to seventeen thousand forty dollars ($17,040). 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. The fee for a temporary license shall be one thousand five hundred dollars ($1,500) and may be increased to two thousand dollars ($2,000).

(w) The fee for the issuance of an outsourcing facility license shall be twenty-five thousand dollars ($25,000) and may be increased to thirty-five thousand two hundred fifty-six dollars ($35,256). The fee for the renewal of an outsourcing facility license shall be twenty-five thousand dollars ($25,000) and may be increased to forty-one thousand three hundred sixty-six dollars ($41,366). The fee for a temporary outsourcing facility license shall be four thousand dollars ($4,000) and may be increased to five thousand six hundred forty-two dollars ($5,642).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars ($28,500) and may be increased to forty-two thousand three hundred eighteen dollars ($42,318). The fee for the renewal of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars ($28,500) and may be increased to forty-six thousand three hundred fifty-three dollars ($46,353). 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. The fee for a temporary nonresident outsourcing license shall be four thousand dollars ($4,000) and may be increased to five thousand six hundred forty-two dollars ($5,642).

(y) The fee for the issuance of a centralized hospital packaging license shall be three thousand eight hundred fifteen dollars ($3,815) and may be increased to five thousand three hundred eighteen dollars ($5,318). The annual renewal of the license shall be two thousand nine hundred twelve dollars ($2,912) and may be increased to four thousand one hundred seven dollars ($4,107).

(z)(1) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) shall be six hundred twenty dollars ($620) and may be increased to eight hundred seventy-three dollars ($873). The annual renewal fee for that correctional clinic license shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561).

(2) The fee for the issuance of an ADDS license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) shall be five hundred dollars ($500) and may be increased to seven hundred five dollars ($705). The annual renewal fee for the correctional clinic ADDS shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561).

(aa) The fee for an ADDS license shall be five hundred twenty-five dollars ($525) and may be increased to seven hundred forty-one dollars ($741). The fee for the annual renewal of the license shall be four hundred fifty-three dollars ($453) and may be increased to six hundred thirty-nine dollars ($639).

(ab) The application and initial license fee for a remote dispensing site pharmacy application shall be one thousand seven hundred thirty dollars ($1,730) and may be increased to two thousand four hundred forty dollars ($2,440). The fee for the annual renewal shall be one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000). The fee for a temporary license shall be eight hundred ninety dollars ($890) and may be increased to one thousand one hundred ninety-nine dollars ($1,199).

(ac) The application and initial license fee to operate EMSADDS shall be one hundred fifty dollars ($150) and may be increased to three hundred eighty dollars ($380) per machine. The fee for the annual renewal shall be two hundred dollars ($200) and may be increased to two hundred seventy-three dollars ($273). The license fee may not be transferred to a different location if the EMSADDS is moved. The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be eight hundred ten dollars ($810) and may be increased to one thousand one hundred forty-three dollars ($1,143).

(ad) The fee for application and issuance of an initial license as a designated paramedic shall be three hundred fifty dollars ($350) and may be increased to four hundred ninety-four dollars ($494). The fee of biennial renewal shall be two hundred dollars ($200) and may be increased to two hundred ninety-two dollars ($292).

(ae) The fee for an application for an advanced pharmacist practitioner license and renewal of advanced pharmacist practitioner license shall be three hundred dollars ($300) and may be increased to four hundred eighteen dollars ($418).

(af)(1) For purposes of this subdivision, “medically underserved area” means a geographic area that does not have within 50 road miles a physical pharmacy that provides in-person patient care services by a pharmacist and serves the general public.

(2) The board shall waive the application fee for a pharmacy that opens a physical pharmacy operating and located in a medically underserved area.

(3) The board may waive the fee for the annual renewal of a license under this chapter if the licensee provides the board with certification of continued operation in the medically underserved area.

(ag) This section shall become operative on January 1, 2025.

4401. Pharmacist: Biennial Renewal

Every pharmacist who desires to retain his or her license on the books of the board shall biennially pay to the executive officer of the board the renewal fee, established by the board, within the limits prescribed by this chapter. In return for the payment of the renewal fee, a certificate of renewal shall be issued.

4402. Cancellation: Of Pharmacist after Non-Renewal for Three Years; All Other Licenses after 60 Days

(a) Any pharmacist license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

(b) (1) Any pharmacist whose license is canceled pursuant to subdivision (a) may obtain a new license if he or she takes and passes the examination that is required for initial license with the board.

(2) The board may impose conditions on any license issued pursuant to this section, as it deems necessary.

(c) A license that has been revoked by the board under former Section 4411 shall be deemed canceled three years after the board's revocation action, unless the board has acted to reinstate the license in the interim.

(d) This section shall not affect the authority of the board to proceed with any accusation that has been filed prior to the expiration of the three-year period.

(e) Any other license issued by the board may be canceled by the board if the license is not renewed within 60 days after its expiration. Any license canceled under this subdivision may not be reissued. Instead, a new application will be required.

4403. Reissuance without Payment of Fees Prohibited

The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.

4404. Reissuance of Lost or Destroyed License; Proof of Loss, etc.

If any license issued under this chapter is lost or destroyed, or if any person desires a reissuance of his or her license, the board may reissue it, subject to Section 4403, upon application therefor, and the submission of satisfactory proof, if required by the board, that the license has been lost or destroyed, or if the license has not been lost or destroyed, upon the surrender of the old license.

4405. Disposition of Fines

All fines recoverable under this chapter shall be paid by the magistrate receiving the same to the board, except where other provision is made in this chapter for the disposition thereof.

4406. Report of Fees Collected

All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the Controller and at the same time the entire

amount shall be paid into the State Treasury and shall be credited to the Pharmacy Board Contingent Fund which is hereby created. This contingent fund shall be available, upon appropriation of the Legislature, for the use of the board.

4407. Compensation of Members

All compensation of members and all other expenses of the board shall be paid out of the examination and registration fees and fines.

4409. Contribution to California Pharmacist Scholarship and Repayment Program at License Renewal

At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4110 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a contribution of at least twenty-five dollars ($25), to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 2 (commencing with Section 128198) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be paid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128198.5 of the Health and Safety Code.

Article 24. Prescription Rates for Medicare Beneficiaries

4425. Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring

(a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Care Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Health Care Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Health Care Services shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Health Care Services shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's

telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

4426. Department of Public Health to Study Reimbursement Rates

The State Department of Public Health shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

Article 25. Automated Drug Delivery System

4427. Definitions of Drugs and Devices

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

4427.1. Requirements for Installation or Operation

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

4427.2. Licensing Requirements

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

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

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

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

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

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

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

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

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

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

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

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

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, to patients while in a licensed acute psychiatric hospital facility, as defined in subdivision (b) of Section 1250 of the Health and Safety Code, or dispensed to patients pursuant to Section 4068, shall be exempt from the requirement of obtaining an ADDS license pursuant to this

section if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in this article. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request.

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

4427.3. Location Requirements

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

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

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

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

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

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

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

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

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

at the location of the ADDS and at the pharmacy holding the ADDS license.

4427.4. Ownership and Operation by Pharmacy

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

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

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

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

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

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

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

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

4427.5. Personnel Training Required

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

4427.6. Requirements for Using APDS

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

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

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

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

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

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

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

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

(b) The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose

use of the APDS meets inclusion criteria established pursuant to subdivision (a).

(c) The APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

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

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

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

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

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

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

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

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

(l) The pharmacy holding the ADDS license for an APDS shall maintain the policies and procedures developed pursuant to

subdivision (a) for three years after the last date of use of that APDS.

4427.65. Locations and Requirements for Operating Automated Unit Dose System (AUDS)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the

pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

4427.7. Self-Assessment and Recordkeeping Requirements

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

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

4427.8. Report to the Legislature During Sunset Evaluation

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

(b) On or before January 1, 2025, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

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

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

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

CHAPTER 9.5, DIVISION 2
Audits of Pharmacy Benefits

4430. Definitions for Audits of Pharmacy Benefits

For purposes of this chapter, the following definitions shall apply:

(a) "Carrier" means a health care service plan, as defined in Section 1345 of the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106 of the Insurance Code.

(b) "Clerical or recordkeeping error" includes a typographical error, scrivener's error, or computer error in a required document or record.

(c) "Extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors actually measured in a sample of claims.

(d) "Health benefit plan" means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of the Health and Safety Code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.

(e) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.

(f) "Maximum allowable cost list" means a list of drugs for which a maximum allowable cost has been established by a pharmacy benefit manager.

(g) "Obsolete" means a drug that may be listed in national drug pricing compendia but is no longer available to be dispensed based on the expiration date of the last lot manufactured.

(h) "Pharmacy" has the same meaning as provided in Section 4037.

(i) “Pharmacy audit” means an audit, either onsite or remotely, of any records of a pharmacy conducted by or on behalf of a carrier or a pharmacy benefits manager, or a representative thereof, for prescription drugs that were dispensed by that pharmacy to beneficiaries of a health benefit plan pursuant to a contract with the health benefit plan or the issuer or administrator thereof. “Pharmacy audit” does not include a concurrent review or desk audit that occurs within three business days of transmission of a claim, or a concurrent review or desk audit if a chargeback or recoupment is not demanded.

(j) “Pharmacy benefit manager” means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

4431. Applicability of Chapter 9.5

(a) Nothing in this chapter shall apply to an audit conducted because a pharmacy benefit manager, carrier, health benefit plan sponsor, or other third-party payer has indications that support a reasonable suspicion that criminal wrongdoing, willful misrepresentation, fraud, or abuse has occurred.

(b) Nothing in this chapter shall apply to an audit conducted by, or at the direction of, the California State Board of Pharmacy, the State Department of Health Care Services, the State Department of Public Health, or the Medicare program.

4432. Compliance

Notwithstanding any other law, a contract that is issued, amended, or renewed on or after January 1, 2013, between a

pharmacy and a carrier or a pharmacy benefit manager to provide pharmacy services to beneficiaries of a health benefit plan shall comply with the provisions of this chapter. This chapter shall not apply to contracts authorized by Section 4600.2 of the Labor Code.

4433. Payment for Pharmacy Audit

(a) An entity conducting a pharmacy audit shall not receive payment or any other consideration on any basis that is tied to the amount claimed or actual amount recovered from the pharmacy that is the subject of the audit. Nothing in this subdivision shall be construed to prevent the pharmacy benefit manager or health benefit plan from charging or assessing the plan sponsor, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The plan sponsor and the pharmacy benefit manager or health benefit plan have a contract that explicitly states the percentage charge or assessment to the plan sponsor.

(2) No commission or financial incentive is paid to an agent or employee of the entity conducting the pharmacy audit based, directly or indirectly, on amounts recouped.

(b) A pharmacy shall not be subject to recoupment of funds for a clerical or recordkeeping error, unless the error resulted in actual financial harm to the pharmacy benefit manager, the carrier, or the beneficiary of a health benefit plan.

4434. Confidentiality; Notification; List of Records Reviewed

(a) Except as otherwise prohibited by state or federal law, an entity conducting a pharmacy audit shall keep confidential any information collected during the course of the audit and shall not share any information with any person other than the carrier, pharmacy benefit manager, or third-party payer for which the audit is being performed. An entity conducting a pharmacy audit shall have access only to previous audit reports relating to a particular pharmacy conducted by or on behalf of the same entity. Nothing in this subdivision shall be construed to authorize access to information that is otherwise prohibited by law.

Nothing in this subdivision shall be construed to prohibit any employer, trust fund, government agency, or any other entity for which the audit is being performed from disclosing its general opinions or conclusions regarding the business practices of the pharmacy based on the audit.

(b) An entity that is not a carrier or pharmacy benefit manager and that is conducting a pharmacy audit on behalf of a carrier or pharmacy benefit manager shall, prior to conducting the audit, notify the pharmacy in writing that the entity and the carrier or pharmacy benefit manager have executed a business associate agreement or other agreement as required under state and federal privacy laws.

(c) An entity conducting a pharmacy audit shall, prior to leaving a pharmacy at the end of an onsite portion of the audit, provide the pharmacist in charge with a complete list of records reviewed to allow the pharmacy to account for disclosures as required by state and federal privacy laws.

4435. Time of Audit; Notice

(a) An entity conducting an onsite pharmacy audit shall not initiate or schedule a pharmacy audit during the first five business days of any calendar month, unless it is expressly agreed to by the pharmacy being audited.

(b) An entity conducting an onsite pharmacy audit shall provide the pharmacy at least two weeks' prior written notice before conducting an initial audit.

4436. Pharmacy audit involving clinical judgment; legal validity of prescription or other record

(a) A pharmacy audit that involves clinical judgment shall be conducted by, or in consultation with, a licensed pharmacist.

(b) An entity conducting a pharmacy audit shall make all determinations regarding the legal validity of a prescription or other record consistent with determinations made pursuant to Article 4 (commencing with Section 4070) of Chapter 9.

(c) Nothing in this section shall be construed to prohibit a pharmacy benefits manager from denying a claim, either in

whole or in part, for failure to comply with federal Food and Drug Administration or manufacturer requirements, the prescription drug formulary, prior authorization requirements, days' supply requirements, or other coverage or plan design requirement, or for failure to include a National Provider Identification number.

(d) An entity conducting a pharmacy audit shall accept paper or electronic signature logs that document the delivery of pharmacy services to a health plan beneficiary or his or her agent.

4437. Time Period Covered

The time period covered by a pharmacy audit shall not exceed 24 months from the date that the claim was submitted to, or adjudicated by, the pharmacy benefits manager, unless a longer period is required under state or federal law or unless the originating prescription is required.

4438. Preliminary audit report; final audit report

(a)(1) An entity conducting a pharmacy audit shall deliver a preliminary audit report to the pharmacy before issuing a final audit report. This preliminary report shall be issued no later than 60 days after conclusion of the audit.

(2) A pharmacy shall be provided a time period of at least 30 days following receipt of the preliminary audit report under paragraph (1) to respond to the findings in the report, including addressing any alleged mistakes or discrepancies and producing documentation to that effect.

(3) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician and surgeon, or other authorized prescriber, or additional documentation parameters located in the provider manual.

(4) Any legal prescription may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations, or documented

telephone calls from the prescriber or the prescriber's agent. Unless specifically addressed in the audit policies and procedures contained in the contract or provider manual, documentation of an oral prescription order that has been verified by the prescriber shall meet the requirements of this subdivision.

(5) If an entity conducting a pharmacy audit uses extrapolation to calculate penalties or amounts to be recouped, the pharmacy may present evidence to validate orders for dangerous drugs or devices that are subject to invalidation due to extrapolation.

(6) Prior to issuing a final audit report, an entity conducting a pharmacy audit shall take into consideration any response by the pharmacy to the preliminary audit report provided within the timeframes allowed under this section, unless otherwise agreed to by the entity conducting the audit.

(b)(1) An entity conducting a pharmacy audit shall deliver a final audit report to the pharmacy no later than 120 days after receipt of a pharmacy's response to the preliminary audit report.

(2) An entity conducting a pharmacy audit shall establish, in the contract between the pharmacy and the contracting entity, a process for appealing the findings in a final audit report that complies with the following requirements:

(A) A pharmacy shall be provided a time period of at least 30 days following receipt of the final audit report to file an appeal with the entity identified in the appeal process.

(B) An entity conducting a pharmacy audit shall provide the pharmacy with a written determination of appeal issued by the entity identified in the appeal process, which shall be appended to the final audit report, and a copy of the determination shall be sent to the carrier, health benefit plan sponsor, or other third-party payer.

(C) If, following the appeal, either party is not satisfied with the appeal, the party may seek relief under the terms of the contract.

(c) An entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, shall not attempt to make chargebacks or seek recoupment from a pharmacy, or assess or collect penalties from a pharmacy, until the time period for filing

an appeal to a final audit report has passed, or until the appeal process has been exhausted, whichever is later. Should the identified discrepancy for a single audit exceed thirty thousand dollars ($30,000), future payments to the pharmacy in excess of thirty thousand dollars ($30,000) may be withheld pending adjudication of an appeal.

(d) Interest shall not accrue during the audit period for either party, beginning with the notice of the audit and ending with the conclusion of the appeal process.

(e) If, following final disposition of a pharmacy audit pursuant to this section, an entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, finds that an audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion thereof without the necessity of any further proceedings.

4439. Jurisdiction

This chapter shall not be construed to suggest or imply that the Department of Consumer Affairs or the California State Board of Pharmacy has any jurisdiction or authority over the provisions of this chapter.

4440. Compliance; Reimbursing Contracting Pharmacy for Drug on Maximum Allowable Cost Basis

(a) A pharmacy benefit manager that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis shall comply with this section.

(b) A pharmacy benefit manager shall include in a contract, initially entered into, or renewed on its scheduled renewal date, on or after January 1, 2016, with the contracting pharmacy information identifying any national drug pricing compendia or other data sources used to determine the maximum allowable cost for the drugs on a maximum allowable cost list.

(c) A pharmacy benefit manager shall make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost list or lists used by the pharmacy

benefit manager for patients served by that pharmacy in a readily accessible, secure, and usable Web-based format or other comparable format.

(d) A drug shall not be included on a maximum allowable cost list or reimbursed on a maximum allowable cost basis unless all of the following apply:

(1) The drug is listed as "A" or "B" rated in the most recent version of the federal Food and Drug Administration's approved drug products with therapeutic equivalent evaluations, also known as the Orange Book, or has an "NA," "NR," or "Z" rating or a similar rating by a nationally recognized pricing reference, such as Medi-Span or First DataBank.

(2) The drug is generally available for purchase in the state from a national or regional wholesaler.

(3) The drug is not obsolete.

(e) For contracts initially entered into, or renewed on the scheduled renewal date, on or after January 1, 2016, a pharmacy benefit manager shall review and shall make necessary adjustments to the maximum allowable cost of each drug on a maximum allowable cost list using the most recent data sources available at least once every seven days.

(f) For contracts initially entered into, or renewed on the scheduled renewal date, on or after January 1, 2016, a pharmacy benefit manager shall have a clearly defined process for a contracting pharmacy to appeal the maximum allowable cost for a drug on a maximum allowable cost list that includes all of the following:

(1) A contracting pharmacy may base its appeal on either of the following:

(A) The maximum allowable cost for a drug is below the cost at which the drug is available for purchase by similarly situated pharmacies in the state from a national or regional wholesaler.

(B) The drug does not meet the requirements of subdivision (d).

(2) A contracting pharmacy shall be provided no less than 14 business days following receipt of payment for the claim upon which the appeal is based to file an appeal with a pharmacy benefit manager. The pharmacy benefit manager shall make a

final determination regarding a contracting pharmacy's appeal within seven business days of the pharmacy benefit manager's receipt of the appeal.

(3) If an appeal is denied by a pharmacy benefit manager, the pharmacy benefit manager shall provide to the contracting pharmacy the reason for the denial and the national drug code (NDC) of an equivalent drug that may be purchased by a similarly situated pharmacy at the price that is equal to or less than the maximum allowable cost of the appealed drug.

(4) If an appeal is upheld by a pharmacy benefit manager, the pharmacy benefit manager shall adjust the maximum allowable cost of the appealed drug for the appealing contracting pharmacy and all similarly situated contracting pharmacies in the state within one calendar day of the date of determination. The pharmacy benefit manager shall permit the appealing pharmacy to reverse and resubmit the claim upon which the appeal was based in order to receive the corrected reimbursement.

(g) A contracting pharmacy shall not disclose to any third party the maximum allowable cost list and any related information it receives either directly from a pharmacy benefit manager or through a pharmacy services administrative organization or similar entity with which the contracting pharmacy has a contract to provide administrative services for that pharmacy.

4441. Pharmacy benefit managers; Duties; Disclosures

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

(1) "Labeler" means a person or entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Part 207 of Title 21 of the Code of Federal Regulations.

(2) "Proprietary information" means information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel that is held by a pharmacy benefit manager and used for its business purposes.

(3) “Purchaser” means a health benefit plan sponsor or other third-party payer with whom a pharmacy benefit manager contracts to provide the administration and management of prescription drug benefits, except for a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(b) This section shall apply to pharmacy benefit manager contracts that are entered into, amended, or renewed on or after January 1, 2019.

(c)(1) A pharmacy benefit manager shall exercise good faith and fair dealing.

(2) A pharmacy benefit manager has a fiduciary duty to a self-insured employer plan that includes a duty to be fair and truthful toward the client, to act in the client’s best interests, to avoid conflicts of interest, and to perform its duties with care, skill, prudence, and diligence.

(d) A pharmacy benefit manager shall notify a purchaser in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager’s duty to the purchaser to exercise good faith and fair dealing pursuant to subdivision (c).

(e) The pharmacy benefit manager shall, on a quarterly basis, disclose, upon the request of the purchaser, the following information with respect to prescription product benefits specific to the purchaser:

(1) The aggregate wholesale acquisition costs from a pharmaceutical manufacturer or labeler for each therapeutic category of drugs containing three or more drugs, as outlined in the state’s essential health benefits benchmark plan pursuant to Section 1367.005 of the Health and Safety Code.

(2) The aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of drugs containing three or more drugs, as outlined in the state’s essential health benefits benchmark plan pursuant to Section 1367.005 of the Health and Safety Code. The aggregate amount of rebates shall

include any utilization discounts the pharmacy benefit manager receives from a pharmaceutical manufacturer or labeler.

(3) Any administrative fees received from the pharmaceutical manufacturer or labeler.

(4) Whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a pharmaceutical manufacturer to exclusively dispense or provide a drug to a purchaser's employees, insureds, or enrollees, and the application of all consideration or economic benefits collected or received pursuant to that arrangement.

(5) Prescription drug utilization information for the purchaser's enrollees or insureds that is not specific to any individual enrollee or insured.

(6) The aggregate of payments, or the equivalent economic benefit, made by the pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager.

(7) The aggregate of payments made by the pharmacy benefit manager to pharmacies not owned or collected by the pharmacy benefit manager.

(8) The aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, and the application of those amounts collected pursuant to the contract with the purchaser.

(f) The information disclosed pursuant to subdivision (e) shall apply to all retail, mail order, specialty, and compounded prescription products.

(g) Except for utilization information specified in paragraph (5) of subdivision (e), a pharmacy benefit manager is not required to make the disclosures required by subdivision (e) unless and until the purchaser agrees, in writing, to maintain as confidential any proprietary information.

(h) A pharmacy benefit manager shall not impose a penalty or offer an inducement to a purchaser for the purpose of deterring the purchaser from requesting the information set forth in subdivision (e).

(i) A pharmacy benefit manager shall disclose to a pharmacy network provider or its contracting agent any material change to

a contract provision that affects the terms of reimbursement, the process for verifying benefits and eligibility, dispute resolution, procedures for verifying drugs included on the formulary, and contract termination at least 30 days before the date of the change to the provision.

(j) A pharmacy benefit manager shall not notify an individual receiving benefits through the pharmacy benefit manager that a pharmacy has been terminated from the pharmacy benefit manager's network until the notification of termination has been provided to that pharmacy pursuant to subdivision (i).

(k) A pharmacy benefit manager shall not include in a contract with a pharmacy network provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

(*l*) This section shall not apply to the following:

(1) A health care service plan or health insurer, if the health care service plan or health insurer offers, provides, or administers pharmacy benefit management services and if those services are offered, provided, or administered only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered, provided, or administered by that health care service plan or health insurer.

(2) An affiliate, subsidiary, related entity, or contracted medical group of a health care service plan or health insurer that would otherwise qualify as a pharmacy benefit manager, but offers, provides, or administers services only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered, provided, or administered by the health care service plan or health insurer.

(3) A contract authorized by Section 4600.2 of the Labor Code.

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

Additional Pharmacy Benefit Manager Licensee Requirements can be found under Division 2, Chapter 2.2, Article 6.1 of the

Health and Safety Code and Division 2, Part 2, Chapter 1, Article 1 of the Insurance Code, among others.

OTHER IMPORTANT SECTIONS OF THE BUSINESS & PROFESSIONS CODE

31. Licensee or Applicant Name on Tax Delinquencies List

(a) As used in this section, "board" means any entity listed in Section 101, the entities referred to in Sections 1000 and 3600, the State Bar, the Department of Real Estate, and any other state agency that issues a license, certificate, or registration authorizing a person to engage in a business or profession.

(b) Each applicant for the issuance or renewal of a license, certificate, registration, or other means to engage in a business or profession regulated by a board who is not in compliance with a judgment or order for support shall be subject to Section 17520 of the Family Code.

(c) "Compliance with a judgment or order for support" has the meaning given in paragraph (4) of subdivision (a) of Section 17520 of the Family Code.

(d) Each licensee or applicant whose name appears on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code shall be subject to Section 494.5.

(e) Each application for a new license or renewal of a license shall indicate on the application that the law allows the State Board of Equalization and the Franchise Tax Board to share taxpayer information with a board and requires the licensee to pay his or her state tax obligation and that his or her license may be suspended if the state tax obligation is not paid.

(f) For purposes of this section, "tax obligation" means the tax imposed under, or in accordance with, Part 1 (commencing with Section 6001), Part 1.5 (commencing with Section 7200), Part 1.6 (commencing with Section 7251), Part 1.7 (commencing with Section 7280), Part 10 (commencing with Section 17001), or Part

11 (commencing with Section 23001) of Division 2 of the Revenue and Taxation Code.

40. Expert Consultant Agreement

(a) Subject to the standards described in Section 19130 of the Government Code, any board, as defined in Section 22, the State Board of Chiropractic Examiners, or the Osteopathic Medical Board of California may enter into an agreement with an expert consultant to do any of the following:

(1) Provide an expert opinion on enforcement-related matters, including providing testimony at an administrative hearing.

(2) Assist the board as a subject matter expert in examination development, examination validation, or occupational analyses.

(3) Evaluate the mental or physical health of a licensee or an applicant for a license as may be necessary to protect the public health and safety.

(b) An executed contract between a board and an expert consultant shall be exempt from the provisions of Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(c) Each board shall establish policies and procedures for the selection and use of expert consultants.

(d) Nothing in this section shall be construed to expand the scope of practice of an expert consultant providing services pursuant to this section.

[Edit. To protect and safeguard consumers and the public in this state, it is necessary that this act take effect immediately—September 26, 2011]

114.5. Applicants; Military Service Inquiry

Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

115.4. Expedited Licensure for Honorably Discharged Member of the Armed Forces

(a) Notwithstanding any other law, on and after July 1, 2016, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces of the United States and was honorably discharged.

(b) Notwithstanding any other law, on and after July 1, 2024, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant is an active duty member of a regular component of the Armed Forces of the United States enrolled in the United States Department of Defense SkillBridge program as authorized under Section 1143(e) of Title 10 of the United States Code.

(c) A board may adopt regulations necessary to administer this section.

115.5. Expedited Licensure Process

(a) A board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:

(1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a license from the board.

(b) A board may adopt regulations necessary to administer this section.

125.3. Recovery of Investigation and Enforcement Costs: Procedures; Proof; Enforcement

(a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licentiate that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licentiate to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(g) (1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licentiate who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licentiate who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(i) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

(k) Notwithstanding the provisions of this section, the Medical Board of California shall not request nor obtain from a physician and surgeon, investigation and prosecution costs for a disciplinary proceeding against the licentiate. The board shall ensure that this subdivision is revenue neutral with regard to it and that any loss of revenue or increase in costs resulting from this subdivision is offset by an increase in the amount of the initial license fee and the biennial renewal fee, as provided in subdivision (e) of Section 2435.

125.9. Citation and Fine

(a) Except with respect to persons regulated under Chapter 11 (commencing with Section 7500), and Chapter 11.6 (commencing with Section 7590) of Division 3, any board, bureau, or commission within the department, the board created by the

Chiropractic Initiative Act, and the Osteopathic Medical Board of California, may establish, by regulation, a system for the issuance to a licensee of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the board, bureau, or commission where the licensee is in violation of the applicable licensing act or any regulation adopted pursuant thereto.

(b) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the board, bureau, or commission exceed five thousand dollars ($5,000) for each inspection or each investigation made with respect to the violation, or five thousand dollars ($5,000) for each violation or count if the violation involves fraudulent billing submitted to an insurance company, the Medi-Cal program, or Medicare. In assessing a fine, the board, bureau, or commission shall give due consideration to the appropriateness of the amount of the fine with respect to factors such as the gravity of the violation, the good faith of the licensee, and the history of previous violations.

(4) A citation or fine assessment issued pursuant to a citation shall inform the licensee that if he or she desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board, bureau, or commission within 30 days of the date of issuance of the citation or assessment. If a hearing is not requested pursuant to this section, payment of any fine shall not constitute an admission of the violation charged. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) Failure of a licensee to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action being taken by the board, bureau, or commission. Where a citation is not contested and a fine is not paid, the full amount of the assessed fine shall be added to the fee for renewal of the license. A license shall not be renewed without payment of the renewal fee and fine.

(c) The system may contain the following provisions:

(1) A citation may be issued without the assessment of an administrative fine.

(2) Assessment of administrative fines may be limited to only particular violations of the applicable licensing act.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the special fund of the particular board, bureau, or commission.

135.4. Expedited Licensure for Refugees, Asylees, and Special Immigrant Visa Holders

(a) Notwithstanding any other law, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that they have been admitted to the United States as a refugee under Section 1157 of Title 8 of the United States Code, have been granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to Section 1158 of Title 8 of the United States Code, or they have a special immigrant visa (SIV) that has been granted a status under Section 1244 of Public Law 110-181, under Public Law 109-163, or under Section 602(b) of Title VI of Division F of Public Law 111-8.

(b) Nothing in this section shall be construed as changing existing licensure requirements. A person applying for expedited licensure under subdivision (a) shall meet all applicable statutory and regulatory licensure requirements.

(c) A board may adopt regulations necessary to administer this section.

139.5 License Application Processing Timeframes

Beginning July 1, 2021, each board, as defined in Section 22, within the department that issues a license shall do both of the following on at least a quarterly basis:

(a) Prominently display on its internet website one of the following:

(1) The current average timeframes for processing initial and renewal license applications.

(2) The combined current average timeframe for processing both initial and renewal license applications.

(b) Prominently display on its internet website one of the following:

(1) The current average timeframes for processing each license type that the board administers.

(2) The combined current average timeframe for processing all license types that the board administers.

144.5. Authority To Receive Certified Records

Notwithstanding any other law, a board described in Section 144 may request, and is authorized to receive, from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. A local or state agency may provide those records to the board upon request.

144.7. Accrediting agencies

(a) For purposes of any code or statute, a national or regional accrediting agency recognized by the United States Department of Education as of January 1, 2025, shall retain that recognition until July 1, 2029, provided that the accrediting agency continues to operate in substantially the same manner as it did on January 1, 2025.

(b) This section shall remain in effect only until January 1, 2030, and as of that date is repealed

148. Unlicensed Activity

Any board, bureau, or commission within the department may, in addition to the administrative citation system authorized by Section 125.9, also establish, by regulation, a similar system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of that board, bureau, or commission. The administrative citation system authorized by this section shall meet the requirements of Section 125.9 and may not be applied to an unlicensed person who is otherwise exempted from the provisions of the applicable licensing act. The establishment of an administrative citation system for unlicensed activity does not preclude the use of other enforcement statutes for unlicensed activities at the discretion of the board, bureau, or commission.

208. CURES Fee Assessment

(a) Beginning April 1, 2025, a Controlled Substance Utilization Review and Evaluation System (CURES) fee of fifteen dollars ($15) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than fifteen dollars ($15) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b)(1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Licensees issued a license that has been placed in a retired or inactive status pursuant to a statute or regulation are exempt from the CURES fee requirement in subdivision (a). This exemption shall not apply to licensees whose license has been placed in a retired or inactive status if the licensee is at any time authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances.
(3) Wholesalers, third-party logistics providers, nonresident wholesalers, and nonresident third-party logistics providers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.
(4) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.
(5) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.
(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).
(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the Podiatric Medical Board of California to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).
(e) This section shall become operative on April 1, 2025.

209. CURES Prescription Drug Monitoring Program; Application and Approval Process

The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that they are applying for licensure or renewing their license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to access reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

315.2. Violation of Probation; Order for Licensee to Cease Practice

(a) A board, as described in Section 315, shall order a licensee of the board to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

315.4. Order Clinical Diagnostic Evaluation for Licensee

(a) A board, as described in Section 315, may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

460. Licensed Department of Consumer Affairs Businesses

(a) No city, county, or city and county shall prohibit a person or group of persons, authorized by one of the agencies in the Department of Consumer Affairs or an entity established pursuant to this code by a license, certificate, or other means to engage in a particular business, from engaging in that business, occupation, or profession or any portion of that business, occupation, or profession.

(b) (1) No city, county, or city and county shall prohibit a healing arts professional licensed with the state under Division 2 (commencing with Section 500) or licensed or certified by an entity established pursuant to this code from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee.

(2) This subdivision shall not be construed to prohibit the enforcement of a local ordinance in effect prior to January 1, 2010, related to any act or procedure that falls within the professionally recognized scope of practice of a healing arts professional licensed under Division 2 (commencing with Section 500).

(c) This section shall not be construed to prevent a city, county, or city and county from adopting or enforcing any local ordinance governing zoning, business licensing, or reasonable health and safety requirements for establishments or businesses of a healing arts professional licensed under Division 2 (commencing with Section 500) or licensed or certified by an entity established under this code or a person or group of persons described in subdivision (a).

(d) Nothing in this section shall prohibit any city, county, or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purpose of covering the cost of regulation.

476. Licensure/Registration Related to Section 31

(a) Except as provided in subdivision (b), nothing in this division shall apply to the licensure or registration of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3, or pursuant to Division 9 (commencing with Section 23000) or pursuant to Chapter 5 (commencing with Section 19800) of Division 8.

(b) Section 494.5 shall apply to the licensure of persons authorized to practice law pursuant to Chapter 4 (commencing with Section 6000) of Division 3, and the licensure or registration of persons pursuant to Chapter 5 (commencing with Section 19800) of Division 8 or pursuant to Division 9 (commencing with Section 23000).

480. Denial of Licenses

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made,

regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

(i) Chapter 6 (commencing with Section 6500) of Division 3.

(ii) Chapter 9 (commencing with Section 7000) of Division 3.

(iii) Chapter 11.3 (commencing with Section 7512) of Division 3.

(iv) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

(v) Division 4 (commencing with Section 10000).

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4,

1203.4a, 1203.41, 1203.42, or 1203.425 of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that the person has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if that person has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or 1203.425 of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with

Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of the applicant's complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's internet website and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

494.5. License Shall Not be Issued, Reactivated, Reinstated, or Renewed and be Suspended if Named on Certified Tax Delinquencies List

(a) (1) Except as provided in paragraphs (2), (3), and (4), a state governmental licensing entity shall refuse to issue, reactivate, reinstate, or renew a license and shall suspend a license if a licensee's name is included on a certified list.

(2) The Department of Motor Vehicles shall suspend a license if a licensee's name is included on a certified list. Any reference in this section to the issuance, reactivation, reinstatement, renewal,

or denial of a license shall not apply to the Department of Motor Vehicles.

(3) The State Bar of California may recommend to refuse to issue, reactivate, reinstate, or renew a license and may recommend to suspend a license if a licensee's name is included on a certified list. The word "may" shall be substituted for the word "shall" relating to the issuance of a temporary license, refusal to issue, reactivate, reinstate, renew, or suspend a license in this section for licenses under the jurisdiction of the California Supreme Court.

(4) The Alcoholic Beverage Control Board may refuse to issue, reactivate, reinstate, or renew a license, and may suspend a license, if a licensee's name is included on a certified list.

(b) For purposes of this section:

(1) "Certified list" means either the list provided by the State Board of Equalization or the list provided by the Franchise Tax Board of persons whose names appear on the lists of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code, as applicable.

(2) "License" includes a certificate, registration, or any other authorization to engage in a profession or occupation issued by a state governmental licensing entity. "License" includes a driver's license issued pursuant to Chapter 1 (commencing with Section 12500) of Division 6 of the Vehicle Code. "License" excludes a vehicle registration issued pursuant to Division 3 (commencing with Section 4000) of the Vehicle Code.

(3) "Licensee" means an individual authorized by a license to drive a motor vehicle or authorized by a license, certificate, registration, or other authorization to engage in a profession or occupation issued by a state governmental licensing entity.

(4) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420, the office of the Attorney General, the Department of Insurance, the Department of Motor Vehicles, the State Bar of California, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing an individual to engage in a profession or occupation, including any

certificate, business or occupational license, or permit or license issued by the Department of Motor Vehicles or the Department of the California Highway Patrol. "State governmental licensing entity" shall not include the Contractors' State License Board.

(c) The State Board of Equalization and the Franchise Tax Board shall each submit its respective certified list to every state governmental licensing entity. The certified lists shall include the name, social security number or taxpayer identification number, and the last known address of the persons identified on the certified lists.

(d) Notwithstanding any other law, each state governmental licensing entity shall collect the social security number or the federal taxpayer identification number from all applicants for the purposes of matching the names of the certified lists provided by the State Board of Equalization and the Franchise Tax Board to applicants and licensees.

(e) (1) Each state governmental licensing entity shall determine whether an applicant or licensee is on the most recent certified list provided by the State Board of Equalization and the Franchise Tax Board.

(2) If an applicant or licensee is on either of the certified lists, the state governmental licensing entity shall immediately provide a preliminary notice to the applicant or licensee of the entity's intent to suspend or withhold issuance or renewal of the license. The preliminary notice shall be delivered personally or by mail to the applicant's or licensee's last known mailing address on file with the state governmental licensing entity within 30 days of receipt of the certified list. Service by mail shall be completed in accordance with Section 1013 of the Code of Civil Procedure.

(A) The state governmental licensing entity shall issue a temporary license valid for a period of 90 days to any applicant whose name is on a certified list if the applicant is otherwise eligible for a license.

(B) The 90-day time period for a temporary license shall not be extended. Only one temporary license shall be issued during a regular license term and the term of the temporary license shall coincide with the first 90 days of the regular license term. A

license for the full term or the remainder of the license term may be issued or renewed only upon compliance with this section.

(C) In the event that a license is suspended or an application for a license or the renewal of a license is denied pursuant to this section, any funds paid by the applicant or licensee shall not be refunded by the state governmental licensing entity.

(f) (1) A state governmental licensing entity shall refuse to issue or shall suspend a license pursuant to this section no sooner than 90 days and no later than 120 days of the mailing of the preliminary notice described in paragraph (2) of subdivision (e), unless the state governmental licensing entity has received a release pursuant to subdivision (h). The procedures in the administrative adjudication provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the denial or suspension of, or refusal to renew, a license or the issuance of a temporary license pursuant to this section.

(2) Notwithstanding any other law, if a board, bureau, or commission listed in Section 101, other than the Contractors' State License Board, fails to take action in accordance with this section, the Department of Consumer Affairs shall issue a temporary license or suspend or refuse to issue, reactivate, reinstate, or renew a license, as appropriate.

(g) Notices shall be developed by each state governmental licensing entity. For an applicant or licensee on the State Board of Equalization's certified list, the notice shall include the address and telephone number of the State Board of Equalization, and shall emphasize the necessity of obtaining a release from the State Board of Equalization as a condition for the issuance, renewal, or continued valid status of a license or licenses. For an applicant or licensee on the Franchise Tax Board's certified list, the notice shall include the address and telephone number of the Franchise Tax Board, and shall emphasize the necessity of obtaining a release from the Franchise Tax Board as a condition for the issuance, renewal, or continued valid status of a license or licenses.

(1) The notice shall inform the applicant that the state governmental licensing entity shall issue a temporary license, as provided in subparagraph (A) of paragraph (2) of subdivision (e), for 90 calendar days if the applicant is otherwise eligible and that upon expiration of that time period, the license will be denied unless the state governmental licensing entity has received a release from the State Board of Equalization or the Franchise Tax Board, whichever is applicable.

(2) The notice shall inform the licensee that any license suspended under this section will remain suspended until the state governmental licensing entity receives a release along with applications and fees, if applicable, to reinstate the license.

(3) The notice shall also inform the applicant or licensee that if an application is denied or a license is suspended pursuant to this section, any moneys paid by the applicant or licensee shall not be refunded by the state governmental licensing entity. The state governmental licensing entity shall also develop a form that the applicant or licensee shall use to request a release by the State Board of Equalization or the Franchise Tax Board. A copy of this form shall be included with every notice sent pursuant to this subdivision.

(h) If the applicant or licensee wishes to challenge the submission of his or her name on a certified list, the applicant or licensee shall make a timely written request for release to the State Board of Equalization or the Franchise Tax Board, whichever is applicable. The State Board of Equalization or the Franchise Tax Board shall immediately send a release to the appropriate state governmental licensing entity and the applicant or licensee, if any of the following conditions are met:

(1) The applicant or licensee has complied with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, as described in Section 6832 or 19008 of the Revenue and Taxation Code, to satisfy the unpaid taxes.

(2) The applicant or licensee has submitted a request for release not later than 45 days after the applicant's or licensee's receipt of a preliminary notice described in paragraph (2) of subdivision (e),

but the State Board of Equalization or the Franchise Tax Board, whichever is applicable, will be unable to complete the release review and send notice of its findings to the applicant or licensee and state governmental licensing entity within 45 days after the State Board of Equalization's or the Franchise Tax Board's receipt of the applicant's or licensee's request for release. Whenever a release is granted under this paragraph, and, notwithstanding that release, the applicable license or licenses have been suspended erroneously, the state governmental licensing entity shall reinstate the applicable licenses with retroactive effect back to the date of the erroneous suspension and that suspension shall not be reflected on any license record.

(3) The applicant or licensee is unable to pay the outstanding tax obligation due to a current financial hardship. "Financial hardship" means financial hardship as determined by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, where the applicant or licensee is unable to pay any part of the outstanding liability and the applicant or licensee is unable to qualify for an installment payment arrangement as provided for by Section 6832 or Section 19008 of the Revenue and Taxation Code. In order to establish the existence of a financial hardship, the applicant or licensee shall submit any information, including information related to reasonable business and personal expenses, requested by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, for purposes of making that determination.

(i) An applicant or licensee is required to act with diligence in responding to notices from the state governmental licensing entity and the State Board of Equalization or the Franchise Tax Board with the recognition that the temporary license will lapse or the license suspension will go into effect after 90 days and that the State Board of Equalization or the Franchise Tax Board must have time to act within that period. An applicant's or licensee's delay in acting, without good cause, which directly results in the inability of the State Board of Equalization or the Franchise Tax Board, whichever is applicable, to complete a review of the applicant's or licensee's request for release shall not constitute

the diligence required under this section which would justify the issuance of a release. An applicant or licensee shall have the burden of establishing that he or she diligently responded to notices from the state governmental licensing entity or the State Board of Equalization or the Franchise Tax Board and that any delay was not without good cause.

(j) The State Board of Equalization or the Franchise Tax Board shall create release forms for use pursuant to this section. When the applicant or licensee has complied with the tax obligation by payment of the unpaid taxes, or entry into an installment payment agreement, or establishing the existence of a current financial hardship as defined in paragraph (3) of subdivision (h), the State Board of Equalization or the Franchise Tax Board, whichever is applicable, shall mail a release form to the applicant or licensee and provide a release to the appropriate state governmental licensing entity. Any state governmental licensing entity that has received a release from the State Board of Equalization and the Franchise Tax Board pursuant to this subdivision shall process the release within five business days of its receipt. If the State Board of Equalization or the Franchise Tax Board determines subsequent to the issuance of a release that the licensee has not complied with their installment payment agreement, the State Board of Equalization or the Franchise Tax Board, whichever is applicable, shall notify the state governmental licensing entity and the licensee in a format prescribed by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, that the licensee is not in compliance and the release shall be rescinded. The State Board of Equalization and the Franchise Tax Board may, when it is economically feasible for the state governmental licensing entity to develop an automated process for complying with this subdivision, notify the state governmental licensing entity in a manner prescribed by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, that the licensee has not complied with the installment payment agreement. Upon receipt of this notice, the state governmental licensing entity shall immediately notify the licensee on a form prescribed by the

state governmental licensing entity that the licensee's license will be suspended on a specific date, and this date shall be no longer than 30 days from the date the form is mailed. The licensee shall be further notified that the license will remain suspended until a new release is issued in accordance with this subdivision.

(k) The State Board of Equalization and the Franchise Tax Board may enter into interagency agreements with the state governmental licensing entities necessary to implement this section.

(l) Notwithstanding any other law, a state governmental licensing entity, with the approval of the appropriate department director or governing body, may impose a fee on a licensee whose license has been suspended pursuant to this section. The fee shall not exceed the amount necessary for the state governmental licensing entity to cover its costs in carrying out the provisions of this section. Fees imposed pursuant to this section shall be deposited in the fund in which other fees imposed by the state governmental licensing entity are deposited and shall be available to that entity upon appropriation in the annual Budget Act.

(m) The process described in subdivision (h) shall constitute the sole administrative remedy for contesting the issuance of a temporary license or the denial or suspension of a license under this section.

(n) Any state governmental licensing entity receiving an inquiry as to the licensed status of an applicant or licensee who has had a license denied or suspended under this section or who has been granted a temporary license under this section shall respond that the license was denied or suspended or the temporary license was issued only because the licensee appeared on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code. Information collected pursuant to this section by any state agency, board, or department shall be subject to the Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code). Any state governmental licensing entity that discloses on its Internet Web site or other

publication that the licensee has had a license denied or suspended under this section or has been granted a temporary license under this section shall prominently disclose, in bold and adjacent to the information regarding the status of the license, that the only reason the license was denied, suspended, or temporarily issued is because the licensee failed to pay taxes.

(o) Any rules and regulations issued pursuant to this section by any state agency, board, or department may be adopted as emergency regulations in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

The adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, and safety, or general welfare. The regulations shall become effective immediately upon filing with the Secretary of State.

(p) The State Board of Equalization, the Franchise Tax Board, and state governmental licensing entities, as appropriate, shall adopt regulations as necessary to implement this section.

(q) (1) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any information obtained from the State Board of Equalization or the Franchise Tax Board, pursuant to this section, except to inform the public of the denial, refusal to renew, or suspension of a license or the issuance of a temporary license pursuant to this section. The release or other use of information received by a state governmental licensing entity pursuant to this section, except as authorized by this section, is punishable as a misdemeanor. This subdivision may not be interpreted to prevent the State Bar of California from filing a request with the Supreme Court of California to suspend a member of the bar pursuant to this section.

(2) A suspension of, or refusal to renew, a license or issuance of a temporary license pursuant to this section does not constitute denial or discipline of a licensee for purposes of any reporting

requirements to the National Practitioner Data Bank and shall not be reported to the National Practitioner Data Bank or the Healthcare Integrity and Protection Data Bank.

(3) Upon release from the certified list, the suspension or revocation of the applicant's or licensee's license shall be purged from the state governmental licensing entity's Internet Web site or other publication within three business days. This paragraph shall not apply to the State Bar of California.

(r) If any provision of this section or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

(s) All rights to review afforded by this section to an applicant shall also be afforded to a licensee.

(t) Unless otherwise provided in this section, the policies, practices, and procedures of a state governmental licensing entity with respect to license suspensions under this section shall be the same as those applicable with respect to suspensions pursuant to Section 17520 of the Family Code.

(u) No provision of this section shall be interpreted to allow a court to review and prevent the collection of taxes prior to the payment of those taxes in violation of the California Constitution.

(v) This section shall apply to any licensee whose name appears on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code on or after July 1, 2012.

650. Rebates or Discounts for Referral Prohibited

(a) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership,

proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

(c) The offer, delivery, receipt, or acceptance of any consideration between a federally qualified health center, as defined in Section 1396d(l)(2)(B) of Title 42 of the United States Code, and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to the health center entity pursuant to a contract, lease, grant, loan, or other agreement, if that agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center, shall be permitted only to the extent sanctioned or permitted by federal law.

(d) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2 of this code, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall

be unlawful if the prosecutor proves that there was no valid medical need for the referral.

(e) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2 of this code, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, as described in subsections (x) and (y) of Section 1001.952 of Title 42 of the Code of Federal Regulations, as amended October 4, 2007, as published in the Federal Register (72 Fed. Reg. 56632 and 56644), and subsequently amended versions.

(f) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Public Health under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(g) Notwithstanding the other subdivisions of this section or any other provision of law, the payment or receipt of consideration for advertising, wherein a licensee offers or sells services through a third-party advertiser, shall not constitute a referral of patients when the third-party advertiser does not itself recommend, endorse, or otherwise select a licensee. The fee paid to the third-party advertiser shall be commensurate with the service provided by the third-party advertiser. If the licensee determines, after consultation with the purchaser of the service, that the service provided by the licensee is not appropriate for the purchaser or if the purchaser elects not to receive the service for any reason and requests a refund, the purchaser shall receive a refund of the full purchase price as determined by the terms of the advertising service agreement between the third-party advertiser and the licensee. The licensee shall disclose in the advertisement that a consultation is required and that the purchaser will receive a refund if not eligible to receive the service. This subdivision shall not apply to basic health care services, as defined in subdivision (b) of Section 1345 of the Health and Safety Code, or essential health benefits, as defined in Section 1367.005 of the Health and Safety Code and Section

10112.27 of the Insurance Code. The entity that provides the advertising shall be able to demonstrate that the licensee consented in writing to the requirements of this subdivision. A third-party advertiser shall make available to prospective purchasers advertisements for services of all licensees then advertising through the third-party advertiser in the applicable geographic region. In any advertisement offering a discount price for a service, the licensee shall also disclose the regular, nondiscounted price for that service.

(h) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in a county jail for not more than one year, or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding fifty thousand dollars ($50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by that imprisonment and a fine of fifty thousand dollars ($50,000).

650.1. Lease Prohibition – Hospitals or Prescribers

(a) Any amount payable to any hospital, as defined in Section 4028, or any person or corporation prohibited from pharmacy permit ownership by subdivision (a) of Section 4111 under any rental, lease or service arrangement with respect to the furnishing or supply of pharmaceutical services and products, which is determined as a percentage, fraction, or portion of (1) the charges to patients or of (2) any measure of hospital or pharmacy revenue or cost, for pharmaceuticals and pharmaceutical services is prohibited.

(b) Any lease or rental arrangement existing on the effective date of this section shall be in full compliance with subdivision (a) by January 1, 1986.

(c) Any lease or rental agreement entered into prior to January 1, 1980, that extends beyond the effective date of this section shall be construed to be in compliance with this section until its expiration or the expiration of any option which is contained in any such lease or rental agreement provided that the lease or

rental agreement contains provisions which limit pharmacy charges to the amounts not in excess of the prevailing charges in similar hospitals in the general geographic area.

(d) The California State Board of Pharmacy, the Medical Board of California, and the State Department of Health Services shall enforce this section and may require information from any person as is necessary for the enforcement of this section. It shall be the duty of the licensees of the respective regulatory agencies to produce the requisite evidence to show compliance with this section. Violations of this section shall be deemed to be the mutual responsibility of both lessee and lessor, and shall be grounds for disciplinary action or other sanctions against both.

651. **Professional Advertising Requirements**

(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

(1) Contains a misrepresentation of fact.

(2) Is likely to mislead or deceive because of a failure to disclose material facts.

(3) (A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been

altered in any manner from the image of the actual subject depicted in the photograph or image.

(B) Use of any photograph or other image of a model without clearly stating in a prominent location in easily readable type the fact that the photograph or image is of a model is a violation of subdivision (a). For purposes of this paragraph, a model is anyone other than an actual patient, who has undergone the procedure being advertised, of the licensee who is advertising for his or her services.

(C) Use of any photograph or other image of an actual patient that depicts or purports to depict the results of any procedure, or presents "before" and "after" views of a patient, without specifying in a prominent location in easily readable type size what procedures were performed on that patient is a violation of subdivision (a). Any "before" and "after" views (i) shall be comparable in presentation so that the results are not distorted by favorable poses, lighting, or other features of presentation, and (ii) shall contain a statement that the same "before" and "after" results may not occur for all patients.

(4) Relates to fees, other than a standard consultation fee or a range of fees for specific types of services, without fully and specifically disclosing all variables and other material factors.

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

(c) Any price advertisement shall be exact, without the use of phrases, including, but not limited to, "as low as," "and up," "lowest prices," or words or phrases of similar import. Any

advertisement that refers to services, or costs for services, and that uses words of comparison shall be based on verifiable data substantiating the comparison. Any person so advertising shall be prepared to provide information sufficient to establish the accuracy of that comparison. Price advertising shall not be fraudulent, deceitful, or misleading, including statements or advertisements of bait, discount, premiums, gifts, or any statements of a similar nature. In connection with price advertising, the price for each product or service shall be clearly identifiable. The price advertised for products shall include charges for any related professional services, including dispensing and fitting services, unless the advertisement specifically and clearly indicates otherwise.

(d) Any person so licensed shall not compensate or give anything of value to a representative of the press, radio, television, or other communication medium in anticipation of, or in return for, professional publicity unless the fact of compensation is made known in that publicity.

(e) Any person so licensed may not use any professional card, professional announcement card, office sign, letterhead, telephone directory listing, medical list, medical directory listing, or a similar professional notice or device if it includes a statement or claim that is false, fraudulent, misleading, or deceptive within the meaning of subdivision (b).

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

(h) Advertising by any person so licensed may include the following:

(1) A statement of the name of the practitioner.

(2) A statement of addresses and telephone numbers of the offices maintained by the practitioner.

(3) A statement of office hours regularly maintained by the practitioner.

(4) A statement of languages, other than English, fluently spoken by the practitioner or a person in the practitioner's office.

(5) (A) A statement that the practitioner is certified by a private or public board or agency or a statement that the practitioner limits his or her practice to specific fields.

(i) For the purposes of this section, a dentist licensed under Chapter 4 (commencing with Section 1600) may not hold himself or herself out as a specialist, or advertise membership in or specialty recognition by an accrediting organization, unless the practitioner has completed a specialty education program approved by the American Dental Association and the Commission on Dental Accreditation, is eligible for examination by a national specialty board recognized by the American Dental Association, or is a diplomate of a national specialty board recognized by the American Dental Association.

(ii) A dentist licensed under Chapter 4 (commencing with Section 1600) shall not represent to the public or advertise accreditation either in a specialty area of practice or by a board not meeting the requirements of clause (i) unless the dentist has attained membership in or otherwise been credentialed by an accrediting organization that is recognized by the board as a bona fide organization for that area of dental practice. In order to be recognized by the board as a bona fide accrediting organization for a specific area of dental practice other than a specialty area of dentistry authorized under clause (i), the organization shall condition membership or credentialing of its members upon all of the following:

(I) Successful completion of a formal, full-time advanced education program that is affiliated with or sponsored by a university based dental school and is beyond the dental degree at a graduate or postgraduate level.

(II) Prior didactic training and clinical experience in the specific area of dentistry that is greater than that of other dentists.

(III) Successful completion of oral and written examinations based on psychometric principles.

(iii) Notwithstanding the requirements of clauses (i) and (ii), a dentist who lacks membership in or certification, diplomate

status, other similar credentials, or completed advanced training approved as bona fide either by an American Dental Association recognized accrediting organization or by the board, may announce a practice emphasis in any other area of dental practice only if the dentist incorporates in capital letters or some other manner clearly distinguishable from the rest of the announcement, solicitation, or advertisement that he or she is a general dentist.

(iv) A statement of certification by a practitioner licensed under Chapter 7 (commencing with Section 3000) shall only include a statement that he or she is certified or eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board.

(B) A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she limits his or her practice to specific fields, but shall not include a statement that he or she is certified or eligible for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, unless that board or association is (i) an American Board of Medical Specialties member board, (ii) a board or association with equivalent requirements approved by that physician and surgeon's licensing board, or (iii) a board or association with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in that specialty or subspecialty. A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification, unless the physician and surgeon is also licensed under Chapter 4 (commencing with Section 1600) and the use of the term "board certified" in reference to that certification is in accordance with subparagraph (A). A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to

in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. For purposes of this subparagraph, a multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the Medical Board of California, for certifying medical doctors and other health care professionals that is based on the applicant's education, training, and experience.

For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is an American Board of Medical Specialties member board, an organization with equivalent requirements approved by a physician and surgeon's licensing board, or an organization with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in a specialty or subspecialty. The Medical Board of California shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph. The fee shall not exceed the cost of administering this subparagraph. Notwithstanding Section 2 of Chapter 1660 of the Statutes of 1990, this subparagraph shall become operative July 1, 1993. However, an administrative agency or accrediting organization may take any action contemplated by this subparagraph relating to the establishment or approval of specialist requirements on and after January 1, 1991.

(C) A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she is certified or eligible or qualified for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, if that board or association meets one of the following requirements:

(i) is approved by the Council on Podiatric Medical Education,

(ii) is a board or association with equivalent requirements approved by the California Board of Podiatric Medicine, or (iii) is

a board or association with the Council on Podiatric Medical Education approved postgraduate training programs that provide training in podiatric medicine and podiatric surgery. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the California Board of Podiatric Medicine, for certifying doctors of podiatric medicine that is based on the applicant's education, training, and experience. For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is a Council on Podiatric Medical Education approved board, an organization with equivalent requirements approved by the California Board of Podiatric Medicine, or an organization with a Council on Podiatric Medical Education approved postgraduate training program that provides training in podiatric medicine and podiatric surgery.

The California Board of Podiatric Medicine shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph, to be deposited in the State Treasury in the Podiatry Fund, pursuant to Section 2499. The fee shall not exceed the cost of administering this subparagraph.

(6) A statement that the practitioner provides services under a specified private or public insurance plan or health care plan.

(7) A statement of names of schools and postgraduate clinical training programs from which the practitioner has graduated, together with the degrees received.

(8) A statement of publications authored by the practitioner.

(9) A statement of teaching positions currently or formerly held by the practitioner, together with pertinent dates.

(10) A statement of his or her affiliations with hospitals or clinics.

(11) A statement of the charges or fees for services or commodities offered by the practitioner.

(12) A statement that the practitioner regularly accepts installment payments of fees.

(13) Otherwise lawful images of a practitioner, his or her physical facilities, or of a commodity to be advertised.

(14) A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of commodities advertised.

(15) An advertisement of a registered dispensing optician may include statements in addition to those specified in paragraphs (1) to (14), inclusive, provided that any statement shall not violate subdivision (a), (b), (c), or (e) or any other section of this code.

(16) A statement, or statements, providing public health information encouraging preventative or corrective care.

(17) Any other item of factual information that is not false, fraudulent, misleading, or likely to deceive.

(i) Each of the healing arts boards and examining committees within Division 2 shall adopt appropriate regulations to enforce this section in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Each of the healing arts boards and committees and examining committees within Division 2 shall, by regulation, define those efficacious services to be advertised by businesses or professions under their jurisdiction for the purpose of determining whether advertisements are false or misleading. Until a definition for that service has been issued, no advertisement for that service shall

be disseminated. However, if a definition of a service has not been issued by a board or committee within 120 days of receipt of a request from a licensee, all those holding the license may advertise the service. Those boards and committees shall adopt or modify regulations defining what services may be advertised, the manner in which defined services may be advertised, and restricting advertising that would promote the inappropriate or excessive use of health services or commodities. A board or committee shall not, by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

(j) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

(k) A physician and surgeon or doctor of podiatric medicine licensed pursuant to Chapter 5 (commencing with Section 2000) by the Medical Board of California who knowingly and intentionally violates this section may be cited and assessed an administrative fine not to exceed ten thousand dollars ($10,000) per event. Section 125.9 shall govern the issuance of this citation and fine except that the fine limitations prescribed in paragraph (3) of subdivision (b) of Section 125.9 shall not apply to a fine under this subdivision.

652. Violation as Unprofessional Conduct

Violation of this article in the case of a licensed person constitutes unprofessional conduct and grounds for suspension or revocation of his or her license by the board by whom he or she is licensed, or if a license has been issued in connection with a place of business, then for the suspension or revocation of the place of business in connection with which the violation occurs. The proceedings for suspension or revocation shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and each board shall have all the powers granted therein. However, in the case of a licensee of the State Department of Health Services, the proceedings shall be conducted in accordance with Section 110171 of the Health and Safety Code. In addition, any violation constitutes a misdemeanor as to any and all persons offering, delivering, receiving, accepting, or participating in any rebate, refund, commission, preference, patronage dividend, unearned discount, or consideration, whether or not licensed under this division, and is punishable by imprisonment in the county jail not exceeding six months, by a fine not exceeding two thousand five hundred dollars ($2,500), or by both the imprisonment and fine.

652.5. Violation as Misdemeanor

Except as otherwise provided in this article, any violation of this article constitutes a misdemeanor as to any and all persons, whether or not licensed under this division, and is punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both the imprisonment and fine.

680. Health Care Practitioner Identification

(a) Except as otherwise provided in this section, a health care practitioner shall disclose, while working, his or her name and practitioner's license status, as granted by this state, on a name tag in at least 18-point type. A health care practitioner in a practice or an office, whose license is prominently displayed, may

opt to not wear a name tag. If a health care practitioner or a licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the name tag requirement for individual safety or therapeutic concerns. In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title "nurse" in reference to himself or herself and in any capacity, except for an individual who is a registered nurse or a licensed vocational nurse, or as otherwise provided in Section 2800. Nothing in this section shall prohibit a certified nurse assistant from using his or her title.

(b) Facilities licensed by the State Department of Social Services, the State Department of Public Health, or the State Department of Health Care Services shall develop and implement policies to ensure that health care practitioners providing care in those facilities are in compliance with subdivision (a). The State Department of Social Services, the State Department of Public Health, and the State Department of Health Care Services shall verify through periodic inspections that the policies required pursuant to subdivision (a) have been developed and implemented by the respective licensed facilities.

(c) For purposes of this article, "health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under this division or under any initiative act referred to in this division.

733. Dispensing Prescription Drugs and Devices

(a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by their licensing agency.

(b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024,

pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified their employer, in writing, of the drug or class of drugs to which the licentiate objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have

the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) This section applies to emergency contraception drug therapy, over-the-counter contraceptives, and self-administered prescription-only hormonal contraceptives described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

750. Three Day Rule for Narcotic Drug Prescriptions

(a) For purposes of this section, "prescriber" means a person authorized to write or issue a prescription pursuant to Section 11150 of the Health and Safety Code.

(b)(1) Each board that licenses a prescriber shall develop informational and educational material regarding the federal Drug Enforcement Administration's "Three Day Rule," as codified in subsection (b) of Section 1306.07 of Title 21 of the Code of Federal Regulations, in order to ensure prescriber awareness of existing medication-assisted treatment pathways to serve patients with substance use disorder.

(2) Each board shall annually disseminate the informational and educational material developed pursuant to paragraph (1) to each licensed prescriber's email address on file with the board.

(3) Each board shall post the informational and educational material developed pursuant to paragraph (1) on their internet website.

(4) The requirements of this subdivision shall not apply to the Veterinary Medical Board.

(c) The Medical Board of California shall also annually disseminate the informational and educational material it develops pursuant to subdivision (b) to each acute care hospital in the state. The board may disseminate the informational and educational material to each acute care hospital in the state via email.

(d) The department and boards may consult with other state agencies as necessary to implement this section.

805.9. Adverse actions based on another state's law prohibited

(a) A health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code shall not deny staff privileges to, remove from medical staff, or restrict the staff privileges of a person licensed by a healing arts board in this state on the basis of a civil judgment, criminal conviction, or disciplinary action imposed by another state if that judgment, conviction, or disciplinary action is based solely on the application of another state's law that interferes with a person's right to receive sensitive services that would be lawful if provided in this state.

(b) This section does not apply to a civil judgment, criminal conviction, or disciplinary action imposed in another state based upon conduct in another state that would subject a licensee to a similar claim, charge, or action under the laws of this state.

(c) For purposes of this section:

(1) "Healing arts board" means any board, division, or examining committee in the Department of Consumer Affairs that licenses or certifies health professionals.

(2) "Sensitive services" has the same meaning as in Section 56.05 of the Civil Code.

850.1. Adverse actions based on another state's law prohibited

(a) A healing arts board shall not deny an application for licensure or suspend, revoke, or otherwise impose discipline upon a licensee or health practitioner subject to this division on the basis of a civil judgment, criminal conviction, or disciplinary action in another state if that judgment, conviction, or

disciplinary action is based solely on the application of another state's law that interferes with a person's right to receive sensitive services that would be lawful if provided in this state, regardless of the patient's location.

(b) This section does not apply to a civil judgment, criminal conviction, or disciplinary action imposed in another state based upon conduct in another state that would subject an applicant, licensee, or health care practitioner subject to this division to a similar claim, charge, or action under the laws of this state.

(c) For purposes of this section:

(1) "Healing arts board" means any board, division, or examining committee in the Department of Consumer Affairs that licenses or certifies health professionals.

(2) "Sensitive services" has the same meaning as in Section 56.05 of the Civil Code.

852. Provision of care to patient from a state where that care is illegal does not constitute professional misconduct

The performance, recommendation, or provision of any legally protected health care activity, as defined in Section 1798.300 of the Civil Code, by a licensee or a health care practitioner subject to this division acting within their scope of practice, for a patient who resides in a state in which the performance, recommendation, or provision of that legally protected health care activity is illegal, shall not, by itself, constitute professional misconduct under this division or any regulation governing the licensure, certification, or authorization of that licensee or practitioner, nor shall any license, certification, or authorization of a licensee or health care practitioner subject to this division be revoked, suspended, or annulled or otherwise subject to any other penalty or discipline provided in this division solely on the basis that the licensee or health care practitioner performed, recommended, or provided any legally protected health care activity for a patient who resides in a state in which the performance, recommendation, or provision of that legally protected health service is illegal.

2242. Prescribing, Dispensing or Furnishing Dangerous Drugs without Prior Examination and Medical Indication

(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care.

(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of the patient's practitioner, but in any case no longer than 72 hours.

(2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:

(A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.

(B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be.

(3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refill.

(4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code.

4999.8. Artificial Intelligence Definitions

For purposes of this chapter, the following definitions apply:

(a) "Artificial intelligence" or "AI" has the same meaning as set forth in Section 11546.45.5 of the Government Code.

(b) "Generative artificial intelligence" or "GenAI" has the same meaning as set forth in Section 11549.64 of the Government Code.

(c) "Health care profession" means any profession that is the subject of licensure or regulation under this division or under any initiative act referred to in this division.

4999.9. Use of AI in Healthcare

(a)(1) A violation of this chapter is subject to the jurisdiction of the appropriate health care professional licensing board or enforcement agency.

(2) The appropriate health care professional licensing board may pursue an injunction or restraining order to enforce the provisions of this chapter, as authorized by Section 125.5.

(3) Nothing in this section limits the authority for a health care professional licensing board or enforcement agency to pursue any remedy otherwise authorized under the law.

(b) Any provision of this division that prohibits the use of specified terms, letters, or phrases to indicate or imply possession of a license or certificate to practice a health care profession, without at that time having the appropriate license or certificate required for that practice or profession, shall be enforceable against a person or entity who develops or deploys a system or device that uses one or more of those terms, letters, or phrases in the advertising or functionality of an artificial intelligence or generative artificial intelligence system, program, device, or similar technology.

(c) The use of a term, letter, or phrase in the advertising or functionality of an AI or GenAI system, program, device, or similar technology that indicates or implies that the care, advice, reports, or assessments being offered through the AI or GenAI technology is being provided by a natural person in possession of

the appropriate license or certificate to practice as a health care professional, is prohibited.
(d) Each use of a prohibited term, letter, or phrase shall constitute a separate violation of this chapter.

11345.2. Controlling Person for a Registrant

(a) An individual shall not act as a controlling person for a registrant if any of the following apply:

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. If the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or 1203.425 of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date the individual has knowledge of that fact.

(c) This section shall become operative on July 1, 2020.

17500. False or Misleading Statements, Generally

It is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services, professional or otherwise, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other

manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services, professional or otherwise, or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or for any person, firm, or corporation to so make or disseminate or cause to be so made or disseminated any such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, so advertised at the price stated therein, or as so advertised. Any violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both that imprisonment and fine.

22949.92. Grocery and Pharmacy Establishment Closure Definitions

For purposes of this chapter, the following definitions apply:

(a)(1) “Covered establishment” includes a grocery establishment or a pharmacy establishment.

(A) “Grocery establishment” means a retail store operating in this state that meets both of the following requirements:

(i) The retail store sells primarily household foodstuffs for offsite consumption, including, but not limited to, the sale of fresh produce, meats, poultry, fish, deli products, dairy products, canned foods, dry foods, beverages, baked foods, or prepared foods.

(ii) The sale of any other household supplies or other products by the retail store is secondary to the primary purpose of food sales.

(B) “Pharmacy establishment” means a pharmacy as defined in Section 4037 that meets all of the following requirements:

(i) The pharmacy is a chain community pharmacy or an independent community pharmacy as defined in Section 4001.

(ii) The pharmacy is open to the public.

(iii) The pharmacy is not owned by a health facility as defined in Section 1250 of the Health and Safety Code.
(iv) The pharmacy is not a part of a fully integrated delivery system. For purposes of this clause, a “fully integrated delivery system” means a system that includes a physician organization, health facility or health system, and a nonprofit health care service plan that provides health care services to enrollees in a specific geographic region of the state through an affiliate hospital system and an exclusive contract between the nonprofit health care service plan and a single physician organization in each geographic region to provide those medical services.
(2) Nothing in clause (iii) or (iv) of subparagraph (B) of paragraph (1) shall be construed as exempting a chain community pharmacy as defined in Section 4001 from this chapter. However, a pharmacy location owned and operated by a physician organization, health facility or health system, and a nonprofit health care service plan that is part of a fully integrated delivery system is not a store as described in Section 4001.
(b) “Closure” means the cessation or substantial cessation of industrial or commercial operations by a covered establishment.

22949.92.1. Grocery and Pharmacy Establishment Closure Requirements
(a) A covered establishment shall, no later than 45 days before a closure of the covered establishment takes effect, perform all of the following acts:
(1)(A) Provide written notice of the closure to all of the following persons or entities:
(i)(I) The employees of the covered establishment affected by the closure and their authorized representatives if the covered establishment employs more than five employees.
(II) Notwithstanding any other provision of this subdivision, a covered establishment that employs five or fewer employees shall, no later than 30 days before a closure of the covered establishment takes effect, provide written notice of the closure to the employees of the covered establishment affected by the closure.

(ii) The Employment Development Department.
(iii) The State Department of Social Services.
(iv) The local workforce development board of any city and county government within which the closure occurs.
(v) The chief elected official of each city and county government within which the closure occurs.
(vi) The California State Board of Pharmacy, if the covered establishment is a pharmacy establishment.
(B) Notwithstanding any other provision of this subdivision, a covered establishment that is a pharmacy as defined in Section 4037, is owned by a person or entity who owns 15 or fewer pharmacies nationwide, and is not a covered establishment as defined in subdivision (a) of Section 1400.5 of the Labor Code shall not be required to provide written notice pursuant to subparagraph (A) to any of the following persons or entities:
(i) The Employment Development Department.
(ii) The State Department of Social Services.
(iii) The local workforce development board of any city and county government within which the covered establishment is located.
(iv) The chief elected official of each city and county government within which the covered establishment is located.
(C) Notwithstanding any other provision of this subdivision, a covered establishment that is a grocery establishment as defined in subdivision (a) of Section 22949.92, is owned by a person or entity who owns 15 or fewer grocery establishments nationwide, and is not a covered establishment as defined in subdivision (a) of Section 1400.5 of the Labor Code shall not be required to provide written notice pursuant to subparagraph (A) to any of the following persons or entities:
(i) The Employment Development Department.
(ii) The local workforce development board of any city and county government within which the covered establishment is located.
(iii) The chief elected official of each city and county government within which the covered establishment is located.

(D) Notwithstanding any other provision of this subdivision, a covered establishment that is also a covered establishment as defined in subdivision (a) of Section 1400.5 of the Labor Code shall only be considered in compliance with the requirements of clauses (ii), (iv), and (v) of subparagraph (A) if the covered establishment provides a written notice as required and pursuant to the timeframe specified in Section 1401 of the Labor Code.
(2)(A) Post a written notice of the closure in a conspicuous location at the entrance to the covered establishment's premises that includes the planned closure date of the covered establishment.
(B) If the covered establishment is a pharmacy establishment regardless of the number of employees, the written notice described in subparagraph (A) shall also include both of the following:
(i) The name, address, and contact information of the pharmacy establishment where any prescriptions will be transferred.
(ii) The phone number, email address, or internet website where patients may obtain information regarding the process of transferring the prescription to a pharmacy establishment of the patient's choosing.
(3) Take reasonable steps to provide a written notice of the closure in at least one form other than the forms described in paragraphs (1) and (2) that is in a form in which the covered establishment regularly communicates or advertises to its consumers, if the covered establishment is a grocery establishment, or to its patients, if the covered establishment is a pharmacy establishment.
(b) Except as otherwise required under Section 1401 of the Labor Code or any other provision of the law, a covered establishment shall not be required to provide notice pursuant to this section if either of the following circumstances applies:
(1) A closure is necessitated by a physical calamity or act of war.
(2) The closure is caused by business circumstances that were not reasonably foreseeable at the time that notice would have been required.

(c)(1) A covered establishment that violates this section shall be subject to a civil penalty not to exceed ten thousand dollars ($10,000) for each closure, to be assessed and collected in a civil action brought by any person injured by the violation or in a civil action brought in the name of the people of the State of California by the Attorney General, a district attorney, or a city attorney where the covered establishment was located.
(A) In assessing the amount of the civil penalty, the court shall consider relevant circumstances presented by the parties to the case, including, but not limited to, the following circumstances:
(i) The nature and severity of the misconduct.
(ii) The number of violations.
(iii) The length of time over which the misconduct occurred, and the persistence of the misconduct.
(iv) The willfulness of the misconduct.
(v) The defendant's assets, liabilities, and net worth.
(vi) The number of employees employed by the defendant.
(B)(i) If the Attorney General brings the action, one-half of the civil penalty collected shall be paid to the treasurer of the county in which the judgment was entered, and one-half shall be paid to the General Fund.
(ii) If a district attorney brings the action, the civil penalty collected shall be paid to the treasurer of the county in which the judgment was entered.
(iii) If a city attorney brings the action, one-half of the civil penalty collected shall be paid to the treasurer of the city in which the judgment was entered, and one-half shall be paid to the treasurer of the county in which the judgment was entered.
(C) The court shall grant a prevailing plaintiff reasonable attorney's fees and costs.
(2)(A) An employee that does not receive written notice by a covered establishment in violation of this section is entitled to recover in a civil action an additional sum payable as liquidated damages in the amount of one hundred dollars ($100) per employee for each day the rights of an employee under this section are violated and continuing until the violation is cured.

(B) An employee shall only be entitled to either recover the liquidated damages provided for in this paragraph or to enforce a civil penalty as set forth in Section 1403 of the Labor Code, but not both, for the same violation.
(3) Notwithstanding any other provision of this subdivision, a person shall have no right to bring a private cause of action against a covered establishment for a violation of paragraph (3) of subdivision (a).
(d) Except as provided in subparagraph (B) of paragraph (2) of subdivision (c), this section does not preempt or alter any other rights or remedies, including any causes of action, available under any other federal or state law.

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CALIFORNIA CODE OF REGULATIONS
DIVISION 17, TITLE 16

Article 1. General Provisions

1700. Digital Signatures

Consistent with Government Code Section 16.5, in any written communication, application or other document in which a signature is required or used, the Board shall accept digital signatures that meet the requirements set forth in the California Code of Regulations, Title 2, section 22003(a).
NOTE: Authority Cited: Section 40085, Government Code. Reference: Section 6250 16.5, Government Code.

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with all continuing education requirements to renew his or her pharmacist or advanced practice pharmacist license as required by section 1732.5.

(e) Failure to provide under penalty of perjury all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

1702.1. Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual licensee, other than an individual licensed as a pharmacist or an advanced practice pharmacist.

(a) A licensee applying for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.

(1) The licensee shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) The licensee for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, the licensee shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, the licensee shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide under penalty of perjury all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4032, 4038, 4053, 4115, 4202, 4202.5, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

1702.5. Renewal Requirements for Premises or Facilities

This section applies to the renewal of any license held by a premises or facility.

(a) As a condition of renewal, an applicant seeking renewal of a premises or facility license shall report to the board any disciplinary action taken by any government agency since the issuance or last renewal of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4021.5, 4029, 4034, 4037, 4041, 4043, 4044.3, 4107, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.

1703. Delegation of Certain Functions

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; and issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title 1, California Code of Regulations Section 100; and approve waivers pursuant to Section 4076.5(e) of the Business and Professions Code are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

1704. Providing Addresses

(a) Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

(b) Each applicant or person holding a certificate, license, permit, registration or exemption to practice who has an electronic mail address shall provide to the Board that electronic mail address and shall maintain a current electronic mail address, if any, with the Board and shall within 30 days notify the Board of any change

of electronic mail address, giving both the old and new electronic mail address.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4003, 4013, and 4100, Business and Professions Code.

1705. Notification of Bankruptcy, Receivership or Liquidation

Any pharmacy, wholesaler, or manufacturer who makes any assignment for the benefit of creditors or enters into any creditor compromise arrangement, or who files a petition in bankruptcy, or who has a receiver appointed, or who enters into any liquidation or other arrangement which may result in the sale or transfer of drugs, devices or appliances which are required to be sold by a registered pharmacist or other licensee, shall notify the Board immediately in writing of such fact, and shall set forth the following information, if known:

(a) Date of sale or transfer of such drugs, devices or appliances;

(b) Name and address of purchaser;

(c) Inventory of dangerous drugs and devices showing their disposition;

(d) Location of records of manufacture, sale, purchase, and disposition of dangerous drugs and devices.

Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4005, 4024, 4080, 4081 and 4332, Business and Professions Code.

1706. Words of Similar Import

The words "Prescription," "Prescription Service," "Medication," "Prescribed Medication," and "Medicinals" are words of similar or like import to those enumerated in Section 4343, Business and Professions Code.
Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005.

1706.1 Permit Processing Times

"Permit" as defined by the Permit Reform Act of 1981 means any license, certificate, registration, permit or any other form of

authorization required by a state agency to engage in a particular activity or act. Processing times for the board's various programs are set forth below. The actual processing times apply to those persons who take and pass the first available examination.

License or registration type	**Maximum Time in Days for Notification That an Application Incomplete or Deficient; and What is Needed to Correct the Deficiency**	**Maximum Time in Days after Filing a Complete Application in Which the Board Will Notify Applicant of Decision**	**Actual License or Processing Time in Days Based on Two-Year Compilation** **Min Med Max**
Pharmacist License	30	30	67 167 2,192
Foreign Graduate Application	30	30	154 549 1,047
Intern Permit	30	60	1 4 83
Pharmacy Permit	30	60	6 72 305
Clinic Permit	30	60	20 96 325
Non-Resident Pharmacy Permit	30	60	12* 56* 122*
Exemption Certificate	30	60	20 85 185

Hypodermic Distributor's Permit	30	60	7 87 258
Wholesale Drug Permit	30	60	13 88 605
Medical Device Retailer Permit	30	60	
Medical Device Retailer Warehouse Permit	30	60	
Out-of-State Distributor Permit	30	60	1 21 265

*This registration program began January 1, 1989, thus the data are for only one ½ years.
Authority cited: Section 4005, Business and Professions Code. Reference: Section 15376, Government Code.

1706.2. Abandonment of Application Files

(a) An applicant for a premises license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

(b) An applicant for an individual license not included in subdivision (c), (d), or (e) who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and

meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f)(1) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

(e) An applicant for an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, 4208, and 4210, Business and Professions Code.

1706.5. Experimental Programs

In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

(a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan

or program which specifies the particular provisions to be waived, and which has been approved by the Board.

(b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.

(c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: 5005, 4120, 4161, 4162, 4304 and 4400, Business and Professions Code.

1706.6. Temporary Licenses for Military Spouses/Domestic Partners

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

(1) "Disciplined" means that the applicant's license was placed on probation, revoked, suspended, reproved, censured, reprimanded, restricted, limited, or conditioned.

(2) "Jurisdiction" shall mean a California or another state's licensing board or agency, any agency of the federal government, or another territory of the United States.

(3) "Disciplinary proceeding" shall mean any proceeding or investigation under the authority of the licensing jurisdiction pursuant to which a licensee may be disciplined.

(4) "Good standing" shall mean that the applicant has not been disciplined, is not the subject of an unresolved complaint or review procedure and is not the subject of any unresolved disciplinary proceeding.

(5) "Original licensing jurisdiction" shall mean the entity that issued a license to the applicant authorizing the applicant to practice within the same scope for which the applicant seeks a temporary license from the Board.

(6) “License” shall mean a license of the same type that the applicant is applying for, or comparable authority to practice in another state, district, or territory of the United States.

(b) An applicant for a pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL, or a designated paramedic temporary license pursuant to section 115.6 of the Business and Professions Code (“Code”) shall submit a completed application to the Board and meet all of the requirements of this section and section 115.6 of the Code to be eligible for a temporary license. A completed application shall provide the following information:

(1) The applicant’s identifying and contact information:

(A) Applicant’s full legal name ((Last Name) (First Name) (Middle Name) and, if applicable, (Suffix)),

(B) Other name(s) applicant has used or has been known by,

(C) Applicant’s address of record (The address of record may be a post office box number or other alternate address.),

(D) Applicant’s physical address, if different than the applicant’s address of record,

(E) Applicant’s email address,

(F) Applicant’s telephone number,

(G) Applicant’s Social Security Number or Individual Taxpayer Identification Number, and,

(H) Applicant’s birthdate (month, day, and year).

(2) The applicant shall indicate that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders and shall provide the following documentation with the application:

(A) Certificate of marriage or certified declaration/registration of domestic partnership filed with the California Secretary of State or other documentary evidence of legal union with an active duty member of the Armed Forces, and,

(B) A copy of the military orders establishing their spouse or partner’s duty station in California.

(3) The applicant shall disclose whether the applicant holds a current, active, and unrestricted license and provide written verification from the applicant's original licensing jurisdiction that the applicant's license or other comparable authority is in good standing under that jurisdiction. The verification shall include all of the following:

(A) the full legal name of the applicant and any other name(s) the applicant has used or has been known by,

(B) the license type and number issued to the applicant by the original licensing jurisdiction, and relevant law(s) and regulation(s) under which the license was issued,

(C) the name and location of the licensing agency,

(D) the issuance and expiration date of the license, and,

(E) information showing that the applicant's license is currently in good standing.

(4) The applicant shall attest that the applicant meets all of the requirements for temporary licensure as set forth in Business and Professions Code Section 115.6(c)(1) through (5), including that the applicant has not committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the Business and Professions Code or this division at the time the act was committed and that the applicant is aware that a violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the Board of Pharmacy.

(5) The applicant shall also attest that the applicant has not been disciplined by a licensing entity in another jurisdiction and is not the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(6) The applicant shall submit fingerprints for use by and accessible to the Board in conducting criminal history information record checks through the California Department of Justice.

(7) For applicants for a temporary pharmacist license, the applicant has successfully completed the California Practice Standards and Jurisprudence Examination (CPJE).

(8) The applicant shall sign a statement attesting to the fact that the applicant meets all the requirements for the temporary license, and that the information submitted in the application is accurate, to the best of the applicant's knowledge.

(c) In addition to the above requirements, and prior to submission of the application specified in subsection (b), applicants for a temporary pharmacist license must successfully complete the Board's law and ethics examination designated as the California Practice Standards and Jurisprudence Examination (CPJE) for Pharmacists set forth in Section 4200 of the Code, which tests the applicant's knowledge and proficiency in state and federal laws and provisions of safe patient care, and the items set forth in Section 4200.2 and 4200.3 (d) of the Code.

(d) Upon issuance of a temporary license in accordance with Section 115.6(a) of the Code, the Board shall provide written notice to the applicant of the following:

(1) That the temporary license is nonrenewable;

(2) That the license expires 12 months after issuance, upon issuance or denial of a standard license, upon issuance or denial of a license by endorsement, or upon issuance or denial of an expedited license pursuant to Section 115.5 of the Code, whichever occurs first; and,

(3) Any holder of a temporary license desiring to continue their licensure or to practice in California after expiration of their temporary license shall apply for and obtain a standard pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL, or a designated paramedic license, as applicable, in accordance with Sections 4200, 4202, 4210, 4053, 4053.1, 4053.2, and 4202.5 of the Code.

1707. Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver may, on a case-by-case basis, be granted to any entity licensed by the board for storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code. The board may consider space limitations within the pharmacy, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed area, and any other factor presented by the licensee in making its determine.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for noncontrolled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

(1). The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

(2). The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

(3). The date on which a drug was dispensed or refilled;

(4). The prescription number for each prescription; and

(5). The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authority cited: Sections 4005, 4121 and 4122, Business and Professions Code. Reference: Sections 4005, 4121 and 4122, Business and Professions Code.

1707.2. Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all settings:

(1) upon request;

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;

(3) whenever the prescription drug has not previously been dispensed to a patient; or

(4) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(b)(1) When the patient or patient’s agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that:

(A) the patient receives written notice of his or her right to request consultation;

(B) the patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record; and

(C) a pharmacist shall be available (i) to speak to the patient or patient’s agency during any regular hours of operation, within an

average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(2) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Authority cited: Sections 4005, 4076 and 4112, Business and Professions Code. Reference: Sections 4005, 4076 and 4112, Business and Professions Code.

1707.3. Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery.

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems. Authority cited: Sections 4005, 4121 and 4122, Business and Professions Code. Reference: Sections 4005, 4074, 4121 and 4122, Business and Professions Code.

1707.4. Procedures for Refill Pharmacies.

(a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:

(1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.

(2) The prescription container:

(A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and

(B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.

(3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.

(4) Both pharmacies maintain complete and accurate records of the refill, including:

(A) the name of the pharmacist who refilled the prescription;
(B) the name of the pharmacy refilling the prescription; and
(C) the name of the pharmacy that received the refill request.
(5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.
(6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.
(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.
Authority cited: Section 4005, Business & Professions Code.
Reference: Sections 4063, 4076, 4081 and 4333, Business & Professions Code.

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:
(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
(A) Name of the patient
(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer's trade name of the drug, or the generic name and the statement “generic for _____” where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist,
(i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and
(ii) The manufacturer’s name may be listed outside of the patient-centered area.
(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate

dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

1707.6. Notice to Consumers

(a) Every pharmacy shall post a notice containing the text in subsection (b) and shall place the notice in a conspicuous place, physically accessible to a prescription drug consumer (consumer) so that the consumer can easily read the notice, and use the QR code displayed on the notice to obtain language translation of the notice. Such notice shall be posted at all locations where a consumer receives medication. Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) The video screen utilizes QR code technology for the consumer to access translation of the notice, with sufficient display time for consumers to access the QR code; and (5) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice must also include a QR code that assists limited-English-proficient individuals and informs consumers that the QR code may be used to obtain a translation of the notice. Consumers must be able to use the QR code to obtain translation

of the notice in Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese. It shall contain the following text:

KNOW YOUR RIGHTS

California law requires a pharmacist to speak with you upon your request, every time you get a new prescription, and every time you get a new prescription dosage form, strength, or written directions. *Interpreter* services are available to you upon request at no cost.

Before you leave the pharmacy, CHECK:

- The patient name on the label is correct;
- The medication matches the description on the label;
- The name of the medicine and what it does;
- How and when to take the medication, for how long, and what to do if you miss a dose;
- Possible side effects and what you should do if they occur;
- Whether the medication will work safely with other medicines or supplements; and
- What foods, drinks, or activities should be avoided while taking the medicine.

The address and contact information for consumers to send any complaints about the pharmacy:
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100
www.pharmacy.ca.gov.

This pharmacy must provide any medicine or device legally prescribed for you, unless you are unable to pay the cost of the drug or device or the pharmacist determines doing so would be against the law or potentially harmful to the patient's health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese.
Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which they request assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

(d) As an alternative to posting the notice from subdivision (b) in a conspicuous place, pharmacies may instead provide the notice on a patients' written receipt.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

1708.1. Notification of Temporary Closure.
Except for Correctional Pharmacies, a permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information. A temporary closure shall not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days.
Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4032 and 4312, Business and Professions Code.

1708.2. Discontinuance of Business.
Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction.
Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4322 and 4333, Business and Professions Code; and 11205, Health and Safety Code.

1709. Ownership, Management, and Control of Pharmacies and Other Regulated Business Entities.
(a) Each license issued by the board to operate a pharmacy shall reflect the name and address of the pharmacy, the form of ownership, and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the board within 30 days of the change.
(b)(1) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original license

was issued, shall require written notification to the board within 30 days of the transfer.

(2) Any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued, shall require written notification to the board within 30 days of the transfer.

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership and shall require a new application for licensure:

(1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. The new owner shall apply to the board for licensure in advance of the proposed transactions taking place.

(d) If any beneficial interest of a business entity licensed by the board is held in trust, the applicant, licensee, or any person with management or control of the business entity shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and renewal, report the name of any other person in any position with management or control of the business entity;

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to, the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board;

(3) As part of annual renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application;

(4) Include in the application and annual renewal the name, address, phone number, and any email address for each grantor, settlor, trustee, and/or trust protector, as applicable;

(5) Include in the application and annual renewal the name, address, phone number, and any email address for each named

beneficiary of the trust who is age 18 or older. Where the beneficiary is under age 18, the guardian of the beneficiary(ies) shall be identified; and

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the business entity;

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older. Where the beneficiary is under age 18, the guardian of the beneficiary(ies) shall be identified;

(C)The revocation of the trust;

(D)The dissolution of the trust;

(E) Any amendment to the trust since the original application; and

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4037, 4058, 4101, 4110, 4111, 4112, 4113, 4120, 4130, 4131, 4201, 4205, 4207, 4302, 4305, 4307, 4308, and 4330, Business and Professions Code

1709.1. Designation of Pharmacist in Charge.

(a) The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board, and as part of the application and notice process set forth in Section 1709 of this Division ("application"), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course, available on the board's website, within two years prior to the date of application. The PIC shall complete an attestation statement in compliance with this section. For purposes of this section, a completed attestation statement shall include all of the following: name of the proposed pharmacist-in-charge, the individual's license number, a statement that they have read Sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and this section, a statement identifying the date that the proposed PIC took the board's training course,

and a declaration signed under penalty of perjury of the laws of the State of California that the information provided by the individual is true and correct. The board provided Pharmacist-in-Charge Overview and Responsibility training course shall be approximately 1 hour and shall cover:

(1) Legal requirements of the role of a PIC

(2) Legal prohibitions for a pharmacy owner to subvert the PIC

(3) Legal requirements/Overview of the self-assessment process

(4) How to prepare for an inspection

(5) Top violations that result in a Cite and Fine

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.

(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.

(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The interim PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course, identified in subdivision (a) within two years prior to the date of application. The interim PIC shall complete the attestation statement as identified in subdivision (a). The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to

this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.

(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.

(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4036.5, 4081, 4113, 4305 and 4330, Business and Professions Code.

1710. Hospital Pharmacy.

(a) A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.

(b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:

(1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy,

(2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy,

(3) Each cassette or container meets the requirements of Business and Professions Code section 4076,

(4) Both pharmacies are responsible for ensuring that the order has been properly filled.

(5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.

(6) Prescription information shall be electronically transferred between the two pharmacies.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4029, 4076 and 4380, Business and Professions Code.

1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient’s agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient’s agent, or a prescriber, the pharmacist is not

required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

(3) The findings and determinations generated by the quality assurance review; and,

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug

delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125 and 4427.7, Business and Professions Code.

1712. Use of Pharmacist Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4115, Business and Professions Code.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated patient dispensing system (APDS) to deliver prescription medications to patients provided:

(1) A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to that patient.

(2) The APDS has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.

(3) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(4) Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(e) Any pharmacy making use of an APDS shall maintain, and on an annual basis review, written policies and procedures providing for:

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

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS and for which patients, including when consultation is needed.

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

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS.

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

(6) Ensuring the delivery of medications to patients in the event the APDS is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS.

Authority cited: Sections 4005, 4075, and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7, and 4427.8, Business and Professions Code.

1714. Operational Standards and Security.

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The

pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

Authority cited: Sections 4005 and 4116, Business and Professions Code. Reference: Sections 4116 and 4117, Business and Professions Code.

1714.1. Pharmacy Operations during the Temporary Absence of a Pharmacist.

This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial

Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.

If in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

(b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist.

(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission, and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.

(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours.

(g) For the purposes of this section, ancillary staff includes: an intern pharmacist, a pharmacy technician, non-licensed personnel as defined in Section 1793.3 of Title 16 of the California Code of Regulations and a pharmacy technician trainee as defined in Section 4115.5(a) of the Business and Professions Code.

Authority cited: Sections 4005, 4115 and 4116, Business and Professions Code. Reference: Sections 4009, 4115, 4115.5 and 4116, Business and Professions Code; and Sections 512 and 1186, Labor Code.

1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

(a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee currently working, the pharmacy shall make another person who is an employee of the establishment within which the pharmacy is located available to assist the pharmacist. The pharmacy shall:

(1) Designate the name(s) of one or more persons who will be available to assist the pharmacist;

(2) Ensure that each designated person is able, at a minimum, to perform the duties of nonlicensed pharmacy personnel as specified in section 1793.3;

(3) Ensure that each designated person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;

(4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.

(b) A pharmacy shall have and maintain policies and procedures that address the following:

(1) How a pharmacist on duty will be able to identify the person(s) designated as available to assist them, and the required criteria and training for those designated person(s), which shall be consistent with subdivision (a).

(2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.

(c) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section. For purposes of this section, "impacted pharmacy employees" means any employee of the pharmacy, whether the person works within or for the pharmacy owner, who has any duties to prepare for or to execute how or when a pharmacist may seek or obtain assistance pursuant to Business and Professions Code section 4113.5, including any pharmacist, any person who creates or approves pharmacy employees' work schedules, or who designates persons who may assist the pharmacist pursuant to this section.

(d) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4113.5, Business and Professions Code.

1714.5. Dangerous Drugs and Devices Exempt from the Provisions of Chapter 9, Division 2 of the Business and Professions Code.

As provided in Section 4057 of the Business and Professions Code, the listing below shall be exempt from the provisions of Chapter 9, Division 2 of the Business and Professions Code where the sale or furnishing is made to 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:

(a) dangerous devices,

(b) hypodermic needles and syringes,

(c) sterilized sutures,

(d) parenteral solutions of 50 cubic centimeters or over,

(1) sterile water for injection,

(2) dextrose solutions of 10% or less,

(3) ready-made parenteral nutritional solutions,

(4) pre-diluted ready-to-use electrolyte containing solutions,

(5) colloidal and low molecular weight plasma expanders,

(6) Mannitol,

(7) sodium chloride solutions of 5% or less,

(8) alcohol (ethanol) solutions of 10% or less in dextrose infusions,

(e) sterile water U.S.P.,

(f) sterile normal saline solution,

(g) medicinal gases,

(h) inhalation anesthetics,

(i) laboratory chemicals,

(j) non-controlled topical anesthetics,

(k) injectable local anesthetics when in sealed, pre-packaged kits,

(l) topical stains and dyes,

(m) diagnostic agents and contrast medium for X-ray examination,

(n) medicated dressings,

(o) irrigation solutions, and

(p) ophthalmic irrigation solutions.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4057, Business and Professions Code.

1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) A pharmacist-in-charge of a community pharmacy shall assess the pharmacy's compliance with current laws and regulations by using the components of Form 17M-13 (Rev. 1/22) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." As used in this section, a community pharmacy means a pharmacy serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers shall assess compliance with current laws and regulations using the components of Form 17M-14 (Rev. 01/22) entitled "Hospital Pharmacy Self-Assessment." Both forms are hereby incorporated by reference, and contain the following components:

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including:

(A) Name and any license number(s) of the pharmacy and their expiration date(s);

(B) Address, phone number, ownership type, and website address, if applicable, of the pharmacy;

(C) Federal Drug Enforcement Agency (DEA) registration number, its expiration date, and date of most recent DEA inventory;

(D) Hours of operation of the pharmacy; and

(E) Accreditation by third party, if applicable, and dates of accreditation.

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no," or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials on the self-assessment.

(6) The pharmacist-in-charge shall certify on the final page of the self-assessment that they have completed the self-assessment of the pharmacy of which they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature on the self-assessment.

(7) The pharmacy owner or hospital administrator shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of

perjury of the laws of the State of California with an original handwritten signature on the self-assessment.454

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new automated drug delivery system license has been issued.

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.

(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system’s compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) entitled “Automated Drug Delivery System Self Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.

(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:

(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);

(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;

(C) DEA registration number, expiration date, and date of most recent DEA inventory;

(D) Hours of operation of the pharmacy; and

(E) ADDS license number, address, and hours of operation.

(2) The pharmacist-in-charge shall respond “yes”, “no”, or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(3) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing

system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.

1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions.

The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:

(a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.

(b) The above information shall be provided in the following format:

(1) For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(2) For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or one-half inch nine track magnetic

1600 BPI tape or any other medium approved by the Board of Pharmacy, which diskette, tape or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(3) For each pharmacy without the capacity to comply with either subsection (b)(1) or (2), the original triplicate shall be transmitted to the Department of Justice by the end of the month in which the prescription was filled.

For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2).

(4) As to a prescription which is partially filled or dispensed, the period for compliance with subsections (1), (2), or (3) shall be measured from the earlier of the following dates and times: the prescription is either (1) completely dispensed or (2) can no longer be dispensed.

(c) Every pharmacy which has made a submission as required by this section by July 18, 1998, shall receive a reduction of $75 on its next renewal fee for licensure of the pharmacy by the board. Every pharmacy shall be in compliance with this section and Health and Safety Code section 11165 by September 18, 1998.

1715.6. Reporting Drug Loss.

(a) The owner shall submit to the Board a report containing the information in subdivision (b) no later than thirty (30) days after the date of discovery of the following:

(1) Any loss of a controlled substance in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.
(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.
(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft, in addition to the reporting requirements and time frames mandated by Business and Professions Code section 4104.
(3) Any other significant loss as determined by the pharmacist-in-charge, including but not limited to losses deemed significant relative to the dispensing volume of the pharmacy.
(b) All reports under this section shall specify the identity, amount and strength of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

1715.65. Inventory Activities and Reconciliation Reports of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory activities and prepare inventory reconciliation reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.

(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), an inventory reconciliation report shall be prepared for identified controlled substances lost no later than three months after discovery of the reportable loss of that controlled substance. This report shall be completed if the loss is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of that controlled substance before the loss was discovered through the date of discovery. At a minimum, a reportable loss is as specified in section 1715.6, or any pattern(s) of loss(es) identified by the pharmacist in charge, as defined by the pharmacy's policies and procedures. A reportable loss shall require an inventory reconciliation report for each pattern of loss identified.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions sufficient to identify loss of controlled substances. The functions sufficient to identify loss outside of the inventory reconciliation process shall be identified within the pharmacy's policies and procedures.

(b) The pharmacist-in-charge of a pharmacy or consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory reconciliation reports required by this section.

(c) An inventory reconciliation report prepared pursuant to this section shall include all of the following:

(1) A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the pharmacy or clinic has in inventory, except as provided in

subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal controlled substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) Identification of all records used to compile the report, which shall be maintained in the pharmacy or clinic pursuant to subdivision (e)(2);

(5) Identification of each individual involved in preparing the report; and

(6) Possible causes of overages.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances.

(e)(1) An inventory reconciliation report shall be dated and signed by the pharmacist-in-charge or professional director (if a clinic), in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report.

The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).
(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years.

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible, an outgoing pharmacist-in-charge should also complete an inventory reconciliation report for those controlled substances.

(g) Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on, a quarterly basis. The report or reports shall include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storge area in the hospital under the pharmacy's control.

(h) If an inpatient hospital pharmacy or licensed correctional pharmacy uses an automated drug delivery system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count.:
Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4110, 4113, 4180, 4181, 4182, 4186, 4190, 4191, 4192, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

1716. Variation from Prescriptions.

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-

accepted pharmaceutical practice in the compounding or dispensing of a prescription.
Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4040, Business and Professions Code.

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia. Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, “store in a cool, dry place.”

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing

pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.25. Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;

(5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

1717.1. Common Electronic Files.

(a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.

(b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.

(c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.

(d) Common electronic files as authorized by this section shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

(e) Pharmacies maintaining a common electronic file authorized by this section shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

1717.3. Preprinted Multiple Checkoff Prescription Blanks.

(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

(c) "Preprinted multiple checkoff prescription blank," as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription order for that drug.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4040, Business and Professions Code; and Section 11164, Health and Safety Code.

1717.4. Electronic Transmission of Prescriptions.

(a) Except as otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber to the pharmacy.

(b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.

(c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.

(d) An “interim storage device” means as electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.

(e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.

(f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

(g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.

(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.

1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescriptions provided the pharmacy complies with this section.

(1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section.

(2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program for each new prescription wherein there is a change in the prescription medication, strength, dosage form, or directions for use.

(3) For each prescription to be refilled through the program, the pharmacy shall obtain annual renewal of each prescription from the patient or patient's agent no later than 12 months after the prescription was enrolled in the program.

(4) The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.

(5) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(6) Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.

(7) The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.

(8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy was notified that the patient did not want the refill, regardless of the reason, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication.

(9) A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.

(b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescriptions for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescriptions for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

1718. Current Inventory Defined.

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081 and 4332, Business and Professions Code.

1718.1. Manufacturer's Expiration Date.

All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4005 and 4342, Business and Professions Code.

Article 3. Pharmacist Candidates

1719. Recognized Schools of Pharmacy.

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4200 of the Business and Professions Code.

1720. Application for Pharmacist Examination and Licensure.

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.

(b) The fee required by subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.

(c) Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200 and 4200.2, Business and Professions Code.

1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Equivalency Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 851 and 4200, Business and Professions Code.

1721. Dishonest Conduct during Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for three years from the date of the incident, and shall surrender his or her intern license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123, 496 and 4200, Business and Professions Code.

1723.1. Confidentiality of Examination Questions

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination

to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 123 and 496, business and Professions Code.

1724. Passing Grade in Pharmacist Examination.

In order to pass the examination, an applicant shall be required to obtain a passing score as determined by a criterion-referenced method of establishing the passing point on each part of the examination. The board may scale the passing score to 75 for the purpose of releasing scores to examinees.
Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4200, Business and Professions Code.

1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a recognized school of pharmacy.

(b) A final examination must be a part of the course of study.

(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.
Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4200.1, Business and Professions Code.

1726. Supervision of Intern Pharmacists.

(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.

(b) The pharmacist supervising an intern pharmacist shall provide the experience necessary for the intern pharmacist to become proficient in the practice of pharmacy.

Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

1727.1 Intern Pharmacist Address.

The board shall not make an intern pharmacist's address publicly available on the "Internet," as defined by Business and Professions Code section 17538.

Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005, 4030, 4100 and 4208, Business and Professions Code.

1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank-Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4207 and 4208, Business and Professions Code.

1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(5) A sealed, original Self Query Report from the National Practitioner Data Bank-Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the boar to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005, Business and Professions Code. Reference: Sections 144, 851, and 4200, Business and Professions Code.

Article 3.5. Advanced Practice Pharmacist

1730. Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, subdivision (a)(2)(A).

Authority cited: Sections 4005 and 4210, Business and Professions Code. Reference: Section 4210, Business and Professions Code.

1730.1. Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsections.

(1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), by providing either:

(A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B), by providing either:

(A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate

institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must include no fewer than 1,500 hours of experience providing clinical services to patients. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(A) A written statement from the applicant attesting under penalty of perjury that he or she has:

(i) Earned the clinical experience within the required time frame; and

(ii) Completed the required number of hours of experience providing clinical services to patients, as specified in subsection (a)(3).

(I)The applicant shall provide a copy of the collaborative practice agreement or protocol.

(II)If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least 1,500 hours of experience providing clinical services to patients. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.
Authority cited: Sections 4005 and 4210, Business and Professions Code. Reference: Sections 4052.1, 4052.2 and 4210, Business and Professions Code

1730.2. Certification Programs

(a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned.

(b) For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:

(1) The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;

(2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant's understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;

(3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:

(A) An advanced practice pharmacist licensed by the board or

(B) An expert with experience in the respective area(s) of focus specified in subparagraph (1), where "expert" means a person who qualifies to teach at a school of pharmacy recognized by the board.

(4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and

(5) The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.

Authority cited: Section 4005 and 4210, Business and Professions Code. Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.

Article 4. Continuing Education

1732. Definitions.

As used in this article:

(a) "Accreditation agency" means an organization which evaluates and accredits providers of continuing education for pharmacists.

(b) "Hour" means at least 50 minutes of contact time.

(c) "Provider" means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved as accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board; and

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: section 4005, Business and Professions Code.
Reference: section 4232, Business and Professions Code.

1732.1. Requirements for Accredited Providers.

(a) No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.

(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.

(c) Providers shall furnish statements of credit to all participants that complete a continuing education course. The statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.

(d) Each provider shall notify the accreditation agency at least 15 days in advance of the first time each new continuing education course is offered or presented.

(e) Providers shall maintain records of completion of their continuing education courses for four years.

(f) Providers shall include the following information in promotional materials regarding continuing education courses:

(1) Provider's name.

(2) The number of hours awarded for completion of the course.

(3) The date when the course’s accreditation expires.

(4) The provider number assigned by the accreditation agency.

(5) The name of the provider’s accrediting agency.

(6) The learning objectives of the program.

(7) The nature of the targeted audiences that may best benefit from participation in the program.

(8) The speakers and their credentials.

(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

1732.2. Board Accredited Continuing Education.

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the

individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.2, 4202, 4231 and 4232, Business and Professions Code.

1732.3. Requirements for Continuing Education Courses.

(a) Unless denied by the accreditation agency upon audit, all coursework offered by providers may be used to satisfy the continuing education required by section 1732.5 of this Division.

(b) On a random basis or in response to a request by the board, the accreditation agency shall review selected coursework. The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section.

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.

(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:

(A) The scientific knowledge or technical skills required for the practice of pharmacy.

(B) Direct and/or indirect patient care.

(C) The management and operation of a pharmacy practice.

(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Authority cited: Section 4005 Business and Professions Code. Reference: Section 4232, Business and Professions Code.

1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course, each provider shall submit such materials as are required by the accreditation agency.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the Board, that the applicant has completed 30 hours of continuing education (CE) in the prior 24 months.

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal ("required CE hours") shall be completed by participation in a Board provided CE course in Law and Ethics. At least one (1) hour of the required CE hours shall be completed by participating in a cultural competency course from an accreditation agency approved by the Board pursuant to section 1732.05, covering the specified content areas as required by section 4231 of the Business and Professions Code.

(c) Pharmacists providing specialized patient-care services, as identified in subsections (c)(1)-(4) below, shall complete specialized CE (as part of the required CE hours) as follows:

(1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by section 4052.9 of the Business and Professions Code, if applicable.

(2) At least two (2) hours of approved CE specific to travel medicine, as set forth in section 1746.5 of this Article, if applicable.

(3) At least one (1) hour of approved CE specific to emergency contraception drug therapy, as required by Business and Professions section 4052.3, if applicable.

(4) At least one (1) hour of approved CE specific to immunizations and vaccinations, as set forth in section 1746.4 of this Article, if applicable.

(d) Pharmacists who prescribe any Schedule II controlled substances (as defined in Health and Safety Code section 11055) shall complete at least one (1) hour of the required CE hours by participating in a Board approved CE course once every four (4) years on the risks of addiction associated with the use of Schedule II drugs, as required by section 4232.5 of the Business and Professions Code.

(e) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course demonstrate compliance with the provisions of this section.

(f) “Board approved CE course” shall mean coursework from a provider meeting the requirements of section 1732.1.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052.3, 4052.8, 4052.9, 4231, 4232, and 4232.5, Business and Professions Code.

1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for renewal on the grounds of emergency or hardship by applying to the board in writing, setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4234, Business and Professions Code.

1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

1732.8. Renewal Requirements for Pharmacy Technicians.

(a) As a condition of license renewal, a pharmacy technician licensee shall submit proof satisfactory to the Board that the applicant has completed at least one (1) hour of continuing education (CE) in a cultural competency course covering the specified content areas, from an accreditation agency approved by the Board pursuant to section 1732.05, during the two years preceding the application for renewal, as required by section 4202 of the Business and Professions Code. All pharmacy technicians shall retain their certificate of completion for four (4) years from the date of completion of the cultural competency course to demonstrate compliance with the provisions of this section.

(b) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the Board that the licensee has completed the cultural competency course as required, the Board shall not renew the license and shall issue the applicant an inactive pharmacy technician license.
(c) If, as part of an investigation or audit conducted by the Board, a pharmacy technician fails to provide documentation substantiating the completion of CE as required in subsection (a), the Board shall cancel the active pharmacy technician license and issue an inactive pharmacy technician license in its place. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by submitting renewal fees due and submitting proof satisfactory to the Board that the pharmacy technician has completed the required CE.
NOTE: Authority cited: Sections 462 and 4005, Business and Professions Code. Reference: Sections 462 and 4202, Business and Professions Code.

Article 4.5 Nonsterile Compounding

1735. Compounding Definitions.
In addition to the definitions contained in United States Pharmacopeia (USP) General Chapter 795, titled Pharmaceutical Compounding – Nonsterile Preparations (USP Chapter 795), the following definitions apply to this article and supplement the definitions provided in USP Chapter 795 for compounded nonsterile preparations (CNSPs).
(a) “Approved labeling” means the Food and Drug Administration’s (FDA) approved labeling in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations that includes FDA approved information (as applicable) for the diluent, the resultant strength, the container closure system, and storage time.
(b) “Designated person(s)” means one or more individuals assigned by the pharmacist-in-charge (PIC) to be responsible and

accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations (CNSP) for the purposes of this article). Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.
(c) “Diluent” means a liquid with no pharmacological activity used in reconstitution, such as Purified Water or Sterile Water.
(d) “Essentially a copy” of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.
(e) “Integrity” means retention of strength until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.
(f) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 795.
(g) “Repackaging” means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation of the product or preparation, when the act is not done pursuant to a prescription.
(h) “Strength” means the amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4005 and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4076, 4081, 4126.8, 4169, 4301 and 4332, Business and Professions Code.

1735.1. Introduction and Scope.

In addition to the standards in USP Chapter 795 and section 353a of title 21, United States Code, the compounding of a CNSP that is performed by or through a licensee of the Board shall meet the following requirements of this article.

(a) Nonsterile compounding is performed by or under the direct supervision and control of a licensed pharmacist pursuant to a patient specific prescription, unless otherwise specified in this article.

(b) Reconstitution of a conventionally manufactured drug product that is not done in accordance with the FDA approved directions is considered compounding.

(c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.

(d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of no more than a 14-day supply, for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.

(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:

(1) is essentially a copy of one or more commercially available drug products, unless:

(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time

of compounding or within 60 days of the end of the shortage, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or

(B) the pharmacist verifies and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient.

(C) Documentation describing the conditions in (1)(A) and (1)(B) is maintained in a readily retrievable format.

(2) is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian acting within a valid veterinarian-client-patient relationship (VCPR) determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022, which is hereby incorporated by reference.

(f) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions in section 1707.2, consultation includes proper use, storage, handling, and disposal of the CNSP and related supplies furnished.

A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge compounded medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written

policy about discharge compounded medications that meets the requirements of Business and Professions Code Section 4074.
(h) CNSPs with human whole blood or human whole blood derivatives shall be compounded in compliance with Health and Safety Code section 1602.5.
(i) A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.
Note: Authority cited: Sections 4005 and 4126.8 Business and Professions Code. Reference: Sections 4005, 4051, 4052, 4076, 4081, 4105, 4126.8, 4169, 4301, 4306.5 and 4332, Business and Professions Code; Section 355, Title 21 United States Code; and Part 530, Title 21 Code of Federal Regulations.

1735.2. Personnel Training and Evaluation.
In addition to the standards in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) Training and competency procedures for all personnel who compound or have direct supervision and control of personnel performing compounding or verify compounding preparations shall address the following topics:
(1) Quality assurance and quality control procedures,
(2) Container closure and equipment selection, and
(3) Component selection and handling.
(b) Compounding personnel or persons with direct supervision and control of personnel performing compounding, who fail any aspect of ongoing training and evaluation related to the USP Chapter 795's core competencies shall not be involved in compounding of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.
(c) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in

which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in section 1735.11. Documentation shall be maintained demonstrating compliance.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4051, 4052, 4076, 4081, 4126.8, 4301, 4306.5 and 4332, Business and Professions Code; and Section 353a, Title 21 United States Code.

1735.3. Personnel Hygiene and Garbing.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) Facilities shall require individuals entering the compounding area to report to the supervising pharmacist if they have rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment, per the facility's SOPs. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.
(b) A gown and face mask shall be used whenever a closed system processing device is required.
(c) Disposable garb shall not be shared by personnel and shall be discarded if soiled and after each shift. Gowns intended for reuse during the shift must remain in the compounding area.
(d) Gloves shall be wiped or replaced before beginning a CNSP that contains different components.
(e) Reusable garb and equipment shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol at least daily and before use by different personnel. Any reuseable gowns must be laundered per the facility's SOPs before reuse.
(f) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation.

The records shall be retained in accordance with Business and Professions Code section 4081.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4001.1, 4005, 4081, 4126.8, 4301, 4306.5 and 4332, Business and Professions Code.

1735.4. Building and Facilities.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.
(b) Purified water, distilled water, reverse osmosis water, or higher quality water shall be used for rinsing equipment and utensils.
(c) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the law or the facility's SOPs.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4001.1, 4005, 4126.8, 4169 and 4306.5, Business and Professions Code.

1735.5. Cleaning and Sanitizing.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, as well as the product name(s) of the cleaning and sanitizing agent(s) used.
(b) Any cleaning or sanitizing agents used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301 and 4332, Business and Professions Code.

1735.6. Equipment and Components.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications, where established by the manufacturer.
(b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards, including the manufacturers' specifications and requirements.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8 and 4301, Business and Professions Code.

1735.7. Master Formulation and Compounding Records.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) A CNSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 795 and includes the following additional elements:
(1) If a source is referenced to support the assigned beyond-use date (BUD), the source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.
(2) Instructions for storage and handling of the CNSP.
(b) Where a facility does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself.
(c) A compounding record (CR) shall be maintained and, upon request, produced as a single document developed in compliance with USP Chapter 795, and includes the following additional elements:
(1) The manufacturer, lot number, and expiration date for each component.
(2) The assigned internal identification number, which shall be unique for each CR.

(3) The total quantity or amount compounded, which shall include the number of units made and the volume or weight of each unit, where applicable.
(4) The identity of personnel performing the compounding, the pharmacist who has direct supervision and control of compounding, and the pharmacist verifying the final drug preparation, if different.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4332, Business and Professions Code.

1735.8. Release Inspections and Testing.
In addition to the standards set forth in USP Chapter 795, a pharmacist performing or supervising the nonsterile compounding and the dispensing pharmacist are responsible for the integrity, strength, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label so long as label instructions for storage and handling are followed after the preparation is dispensed.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4076, 4126.8, 4169, 4301 and 4306.5, Business and Professions Code.

1735.9. Labeling.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) A CNSP's label shall also include the following:
(1) Route of intended administration, and
(2) Name of compounding facility and name of dispensing facility (if different).
(b) A CNSP's labeling shall also include:
(1) Any special handling instructions,
(2) Any applicable warning statements, and
(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4016, 4076, 4126.8 and 4301, Business and Professions Code.

1735.10. Establishing Beyond-Use Dates.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. (23:59) on that date.
(b) A CNSP's BUD shall not exceed any of the following:
(1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation,
(2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),
(3) The shortest remaining expiration date or BUD of any of the starting components, unless allowed by USP Chapter 795.
(c) When antimicrobial effectiveness testing is provided by a current FDA-registered drug establishment or an outsourcing facility, the testing must be USP Chapter 51, Antimicrobial Effectiveness Testing, compliant. If such testing is used, or if relying upon current published peer-reviewed literature sources, the reference or test in its entirety shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4169, 4301 and 4332, Business and Professions Code.

1735.11. Standard Operating Procedures (SOPs).
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:
(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) Also describe the following:
(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.
(B) If applicable, procedures for handling, compounding, and disposal of infectious materials. The SOPs shall also describe the facility's protocols for cleanups and spills in conformity with local health jurisdictional standards, if applicable.
(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.
(D) The validated processes for storage, for shipping containers (as applicable), and for transportation of temperature sensitive CNSPs (as applicable) to preserve quality standards for integrity, quality and labeled strength.
(E) The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence.
(F) Actions to be taken if the compounding area or equipment is rendered unusable or in a downtime situation.
(b) The SOPs shall be reviewed on an annual basis by the PIC. Such review shall be documented by the PIC consistent with the facility's SOPs. The SOPs shall be updated any time changes are made to compounding processes, the facility, or other changes occur that impact the CNSP. Such SOP changes shall be disseminated to the affected staff prior to implementation. Documentation of compliance with the subsection shall be maintained for three years.
(c) Failure to follow written SOPs constitutes a basis for enforcement action.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4052, 4081, 4126.8, 4301 and 4332, Business and Professions Code.

1735.12. Quality Assurance and Quality Control.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) The facility's quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include a written procedure for action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.
(b) The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem involving a CNSP.
(c) Consistent with the facility's SOPs, a review shall be initiated of any complaints made to the facility related to a potential quality problem with a CNSP within 72 hours of receipt of the complaint. Such a review shall be documented and dated as defined in the SOPs.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4126.9, 4169, 4301 and 4332, Business and Professions Code.

1735.13. CNSP Packaging and Transporting.
In addition to the standards set forth in USP Chapter 795, the facility shall ensure appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4169 and 4332, Business and Professions Code.

1735.14. Documentation.
In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.
(a) Records shall be maintained as required by USP Chapter 795 and this article in a readily retrievable form for at least three years from the date the record was created or relied upon to meet the requirements of this article. If only recorded and stored electronically, on magnetic media, or in any other computerized

form, the records shall be maintained as specified by Business and Professions Code section 4070.
(b) Records shall be created and maintained in a manner that will provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained for at least three years from the date the record was created, modified, or relied upon, in a readily retrievable format and include all changes to the document, identification of the individual who made each change, and the date of each change.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4332, Business and Professions Code.

1735.15. Flavoring Agents.
(a) In addition to the standards in USP Chapter 795 and section 353a of title 21, United States Code, a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:
(1) Provisions of accommodations as described in Personnel Preparation, Section 3.1 of USP Chapter 795.
(2) Provisions for cleaning and sanitizing designated compounding area when in use.
(3) Provisions to ensure documentation is available and maintained confirming that the quality of the medication is not impacted by adding the flavoring agent.
(4) Provisions for maintaining the elements of the compounding record to ensure information is readily retrievable upon request.
(5) Provisions to ensure the prescription label includes information that a flavoring agent was added.
(6) Provisions to ensure documentation is available to support the establishment of a BUD.
(7) Provisions for reporting to the Board the facility's receipt of a complaint of a potential quality problem involving the CNSP. At a minimum the provisions shall require notification to the Board within 96 hours of receipt of a complaint.
(b) A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage

form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding in the prescription or compounding record.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4332, Business and Professions Code.

Article 4.6 Sterile Compounding

1736. Sterile Compounding Definitions.
The definitions in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding – Sterile Preparations for compounded sterile preparations (CSPs).
(a) "Compounding personnel" means any person involved in any procedure, activity, or direct supervision and control of preparation of CSPs.
(b) "Designated compounding area or compounding area" means a restricted location within a facility that limits personnel access, where only activities and items related to compounding are present.
(c) "Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge (PIC) to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations. Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.
(d) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(e) “Essentially a copy” of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.

(f) “Integrity” means retention of strength until the beyond use date provided on the label, when the preparation is stored and handled according to the label directions.

(g) “Quality” means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 797.

(h) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4057, 4127, 4127.1, 4301 and 4332, Business and Professions Code.

1736.1. Introduction and Scope.

In addition to the standards set forth in USP Chapter 797 and 353a of title 21, United States Code, the following requirements of this article apply to the compounding of a CSP that is performed by or through a licensee of the Board.

(a) For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.

(b)(1) Except as allowed in paragraphs (2) and (3), CSPs for direct and immediate administration as provided in USP Chapter 797 shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such

compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available.

(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures shall be documented in accordance with facility's SOP. Failures requiring use of immediate use provisions shall be reported to the Board within 72 hours of the transition to immediate use provisions.

(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in section 1395i-4(c)(2)(B) of title 42, United States Code, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs. Failures requiring use of immediate use provisions shall be reported to the Board within 72 hours of the transition to immediate use provisions.

(c) Notwithstanding subdivision (a), a limited quantity of CSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for identified patients based on a documented history of prescriptions for that patient population.

(d) A reasonable quantity of a CSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.
(2) for furnishing of not more than a 7-day supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.
(A) With the exception of a topical ophthalmic where up to a 28-day supply may be furnished to veterinarian's office for an individual patient. Such topical ophthalmics shall be compliant with USP Chapter 797 section 14.5, Multiple-Dose CSPs.
(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that:
(1) is essentially a copy of one or more commercially available drug products, unless:
(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or
(B) the pharmacist verifies and documents that the preparation produces a clinically significant difference based on the medical need of an identified individual patient.
(C) Documentation describing the conditions in subsections (1)(A) and (1)(B) is maintained in a readily retrievable format.
(2) is made with any component not suitable for use in a CSP for the intended veterinary population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR) determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compounding shall be done in compliance with the Center for Veterinary Medicine Guidance for Industry #256 –

Compounding Animal Drugs from Bulk Drug Substances issued in August 2022, which is hereby incorporated by reference.
(3) is made with a non-sterile component for which a conventionally manufactured sterile component is available unless the CSP master formula supports such use and is appropriate for the intended CSP.
(4) requires end product sterilization unless sterilization occurs within the same licensed compounding location.
(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.
(g) In addition to the provisions in Section 1707.2 of this Division, consultation includes proper use, storage, handling and disposal of the CSP and related supplies furnished. A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications that meets the requirements of Business and Professions Code Section 4074.
(h) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5. This shall not apply to the compounding of an FDA-approved human whole blood or human whole blood derivative product.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4123, 4126.8, 4127.1 and 4127.2, Business and Professions Code; and Section 353a, Title 21 United States Code.

1736.2. Personnel Training and Evaluation.
In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding.
(a) Training and competency procedures for all personnel who compound or have direct supervision and control of personnel performing compounding shall address the following topics:
(1) Quality assurance and quality control procedures,
(2) Container closure and equipment selection,
(3) Component selection and handling, and
(4) Sterilization techniques, when applicable.
(b) Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Garbing and hand hygiene competencies and aseptic manipulation competencies from one premises may be used for another premises if all of the following conditions are met:
(1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical.
(2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.
(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.
(c) Aseptic manipulation ongoing training and competency shall occur each time and for each staff member involved in an occurrence where the quality assurance program required by the SOPs yields an unacceptable result, as defined in the SOPs, that may indicate microbial contamination of CSPs due to poor practices. Aseptic manipulation ongoing training and competency procedures shall be defined in the facility's SOPs.
(d) Compounding personnel or persons with direct supervision and control of compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency

evaluation shall not be involved in compounding of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct supervision and control of personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct supervision and control of personnel for no more than 30 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.
(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs. Documentation demonstrating compliance with training and competency must be maintained.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4127, 4301 and 4332, Business and Professions Code.

1736.3. Personnel Hygiene and Garbing.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) The pharmacist with supervision and control of compounding shall not allow personnel with potentially contaminating conditions to enter the designated compounding area.
(b) The pharmacist with supervision and control of compounding shall not allow personnel to enter the compounding area with visible non-removable piercings, which could increase the risk of contamination of CSPs.
(c) With the exception of sterile gloves, garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). Sterile gloves shall be donned in a classified room or SCA. Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOPs define specific processes that must be followed to prevent contamination.

(d) Restricted access barrier system and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOPs.
(e) Any garbing accommodations provided by a designated person shall be documented and the documentation shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.4. Facilities and Engineering Controls.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.
(b) If an SCA is used:
(1) Except for walls, the SCA's visible perimeter shall be at least 1 meter from all sides of the PEC, or the SCA can be located in a separate room.
(2) Surfaces within the SCA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.
(c)(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.
(2) The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.
(d) Where a pass-through is installed in a secondary engineering control after [OAL insert effective date], the doors must be interlocking. An existing secondary engineering control that has a pass-through that is not an interlocking device may continue to be used if the SOPs document that two doors may not be opened at the same time.

(e) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs, unless such compounding is being performed consistent with immediate use provisions.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.5. Certification and Recertification.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) Testing and certification of all ISO classified areas shall be completed by a qualified technician knowledgeable with certification methods and procedures outlined in the Controlled Environment Testing Association's (CETA) Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with CETA's Certification Guide for Sterile Compounding Facilities (CAG-003, Revised October 2022), which is hereby incorporated by reference.
(b) CETA standard(s) used to perform certification testing in all ISO classified areas shall be recorded on the report issued by the certifying technician in accordance with the Certification Guide for Sterile Compounding Facilities.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.6. Microbiological Air and Surface Monitoring.
In addition to the requirements in USP Chapter 797, environmental sampling shall be done in compliance with the Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Monitoring for Sterile Compounding Facilities (CAG-009, Revised September 2020), which is hereby incorporated by reference.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

(c) The facility's documentation of each occurrence of the cleaning, disinfecting, and applying of sporicidal disinfectants in the compounding area shall include the identity of the person completing the cleaning and disinfecting as well as the product name(s) of the cleaning, disinfecting, and sporicidal agent(s) used.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.8. Introducing Items into the SEC and PEC.

In addition to the requirements in USP Chapter 797, the following requirement applies to sterile compounding.

Introducing items into the SEC and PEC shall comply with the SOPs as required in section 1736.17.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.9. Equipment, Supplies, and Components.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) All equipment and supplies used to compound a CSP shall be used in accordance with manufacturers' specifications and shall be surface compatible.

(b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers'

specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results shall be reviewed and documented as described in the facility's SOPs.

(c) Any component used to compound a CSP shall be used and stored in accordance with all state and federal laws and the manufacturer's specifications and requirements.

(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP.

(e) All APIs and other components used shall be evaluated for suitability for use in sterile drug preparations, as provided in USP Chapter 797, Section 9.3 Components, and follow the USP drug monograph if one exists. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or other equivalent statement shall not be used to compound for these purposes.

(f) If a component included in the published 503A Category 1 bulk drug substances list is used, it must be found suitable for sterile drug preparations as provided in USP Chapter 797, Section 9.3 Components. The facility's SOPs shall establish a process to determine the quality of the API.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.10. Sterilization and Depyrogenation.
In addition to the requirements in USP Chapter 797, the following requirements apply where applicable.
(a) Dry heat depyrogenation shall be done in compliance with USP Chapter 1228.1, Dry Heat Depyrogenation.
(b) Sterilization by filtration shall be done in compliance with USP Chapter 1229.4, Sterilizing Filtration of Liquids. Filter dimensions and the CSP to be sterilized by filtration shall permit the sterilization process to be completed without the need for replacement of the filter during the process.
(c) Steam sterilization shall be done in compliance with USP Chapter 1229.1, Steam Sterilization by Direct Contact.
(d) Dry heat sterilization shall be done in compliance with USP Chapter 1229.8, Dry Heat Sterilization.
(e) No compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in this section.
(f) Sterilization of supplies and container–closure systems shall be done in compliance with USP Chapter 1229, Sterilization of Compendial Articles.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.11. Master Formulation and Compounding Records.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) A CSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 797 and that record includes the following additional elements:
(1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CSP is dispensed.
(2) Instructions for storage and handling the compounded drug preparation.

(b) When a particular drug preparation is not routinely compounded at a facility, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 797 and this section.
(c) A compounding record (CR) shall be maintained and, upon request, be produced as a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:
(1) The assigned internal identification number, which shall be unique for each CR.
(2) The manufacturer, lot number, and expiration date for each component for the CSP.
(3) The total quantity compounded including the number of units made and either the volume or the weight of each unit.
(4) The identity of personnel performing the compounding, the pharmacist who has direct supervision and control of compounding, and the pharmacist verifying the final drug preparation, if different.
(5) When applicable, endotoxin level calculations and results.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4127 and 4169, Business and Professions Code.

1736.12. Release Inspections and Testing.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) A pharmacist performing or who has direct supervision and control of compounding personnel is responsible for ensuring the integrity, quality, and labeled strength of a CSP until the beyond use date indicated on the label, provided the patient or the patient's agent follows the label instructions provided on the CSP for storage and handling after receiving the CSP.
(b) A pharmacist performing or who has direct supervision and control of compounding personnel is responsible for ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223, Validation of Alternative

Microbiological Methods and shall receive and maintain documentation of the method-suitability for each CSP formulation for which the alternate method is used.
(c) A pharmacist performing or who has direct supervision and control of compounding personnel is responsible for ensuring injectable CSPs made from nonsterile components, regardless of USP Category, are tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results shall be reviewed and documented in the compounding record prior to furnishing.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4127, 4169 and 4332, Business and Professions Code.

1736.13. Labeling.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) A CSP label shall also include all of the following:
(1) Route of intended administration;
(2) For CSPs administered by infusion, the solution utilized;
(3) Instructions for administration;
(A) For CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. A health care facility licensed pursuant to Health and Safety Code Section 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.
(4) Name of compounding facility and dispensing facility (if different).
(b) The label for any CSP dispensed or ready to be dispensed to a patient shall also include the information required by Business and Professions Code section 4076 and section 1707.5. A CSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility shall be labeled with the patient's name, the

directions for the use of the drug, and the date of issuance, but is otherwise exempt from these requirements.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4076, 4123, 4126.8 and 4127, Business and Professions Code.

1736.14. Establishing Beyond-Use Dates.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) A CSP's beyond-use date (BUD) shall not exceed:
(1) The chemical and physical stability data of the active pharmaceutical ingredient(s) and any added substances in the preparation;
(2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions); and
(3) The shortest remaining expiration date or BUD of any of the starting components. Nothing in this paragraph prohibits the allowances in USP Chapter 797, Section 14.2 for pH-altering solutions.
(b) A CSP labeled with a BUD with only a date shall expire at 11:59 p.m. (23:59) on that date.
(c) When sterility or endotoxin testing is required, the pharmacist performing or with direct supervision and control of personnel compounding is responsible for ensuring such testing is performed. Test results shall be reviewed prior to furnishing a CSP. Results must be within acceptable USP limits. Test results shall be retained as part of the compounding record.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4076 and 4126.8 Business and Professions Code.

1736.15. Use of Conventionally Manufactured Products as Components.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A single-dose container entered or punctured outside of an ISO Class 5 area, must be discarded immediately.
(b) A single-dose container entered or punctured inside of an ISO Class 5 area must be discarded within 12 hours.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.16. Use of CSPs as Components.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article and USP Chapter 797 Category 1, Category 2, or Category 3.
(b) Nothing in this section shall prohibit the use of a CSP obtained from a California licensed outsourcing facility.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4127.2 and 4127.8, Business and Professions Code.

1736.17. Standard Operating Procedures (SOPs).
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) Standard operating procedures (SOPs) for sterile compounding shall be followed and shall:
(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and
(2) Define the following:
(A) Methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations;
(B) If applicable, procedures for handling, compounding, and disposal of infectious materials. The SOPs shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards;
(C) The methods used to determine and approve the components and the compounding process for each preparation before

compounding begins, including components referenced in section 1736.9(f); and
(D) The method for complying with all other requirements specifically defined in the SOPS.
(b) The SOPs shall specify the steps to be taken if a classified area(s), including PEC, fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures. This subsection shall also include actions to be taken if the compounding area or equipment is rendered unusable or in downtime situations.
(c) The SOPs shall specify steps to be taken when the microbiological air and surface monitoring action levels are exceeded including the investigative and corrective actions, allowable activities, and resampling procedures.
(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA. These SOPs must define at a minimum what product is to be used, the contact time required, and the method to ensure contact time is achieved.
(e) The SOPs shall specify the frequency and processes for cleaning, maintenance, and calibration of equipment, supplies and components, including when incubation of samples is taking place, such that samples are not compromised. All cleaning, maintenance, and calibration shall be documented and dated as defined in the SOPs.
(f) The SOPs shall specify which pharmacist is responsible for the review of all complaints related to a potential quality problem with a CSP and all adverse drug experiences in the event that the PIC is not available within 72 hours of the receipt of the complaint or occurrence.
(g) There shall be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality, and labeled strength.
(h) The PIC shall review the SOPs on an annual basis. The PIC shall document such review consistent with the SOPs. The SOPs shall

be updated to reflect changes to compounding processes, facility changes, and other changes that impact the CSP. Such SOP changes shall be disseminated to the compounding personnel prior to implementation. Documentation of compliance with the subdivision shall be maintained for three years.
(i) Failure to follow written SOPs shall constitute a basis for enforcement action.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5 and 4332, Business and Professions Code.

1736.18. Quality Assurance and Quality Control.
In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.
(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the facility's quality assurance program shall include the following:
(1) A written procedure for action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.
(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.
(b) Recalls and adverse drug experiences, as defined in section 310.305(b) of title 21, Code of Federal Regulations , reporting shall be completed in compliance with relevant provisions of law.
(c) In addition to subsection (b), the pharmacist-in-charge shall initiate a review of any complaints made to the facility related to a potential quality problem with a CSP and any adverse drug experiences within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4127.2 and 4127.8, Business and Professions Code.

1736.19. CSP Handling, Storage, Packaging, Shipping, and Transport.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

Packaging materials shall protect CSPs from damage and leakage while also preventing transportation personnel from inadvertent exposure.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1736.20. Documentation.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Records shall be maintained as required by USP Chapter 797 and this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained, for at least three years from the date the record was created, modified, or relied upon, in a readily retrievable format and include the changes to the document, identification of the individual who made the change, and the date of each change.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4127 and 4332, Business and Professions Code.

1736.21. Compounding Allergenic Extracts.

In addition to the requirements in USP Chapter 797, the following requirements apply to allergenic extracts.

(a) Any allergenic extract compounding shall take place in a dedicated allergenic extract compounding area (AECA) or PEC. No other CSP may be made in this PEC at the same time allergenic

extract compounding is occurring. Work surface of the PEC must be cleaned and disinfected immediately after allergenic extract compounding.
(b) Compounding of allergenic extracts are limited to patient-specific prescriptions.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

Article 4.7 Hazardous Drugs

1737. Handling of Hazardous Drugs.
In addition to the requirements in United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled Hazardous Drugs – Handling in Healthcare Setting, this article applies to the compounding of Hazardous Drugs (HDs) or crushing or splitting tablets or opening capsules of antineoplastic HDs.
(a) A licensee performing hazardous drug (HD) compounding shall comply with this article as well as the non-sterile and sterile compounding requirements, as applicable, in Article 4.5 and Article 4.6.
(b) Additional safety and health requirements are included in the California Code of Regulations, Title 8, and are enforced by the Division of Occupational Safety and Health.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.1. Introduction and Scope.
In addition to the requirements in USP Chapter 800, the following requirements of this article apply to the compounding of Hazardous Drugs that is performed by or through a licensee of the Board.
In addition to the provisions in section 1707.2, consultation includes handling and disposal of a compounded HD or related supplies furnished. A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and

Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications which meets the requirements of Business and Professions Code Section 4074.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.2. List of Hazardous Drugs.
In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.
(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the pharmacist-in-charge (PIC), or the professional director of a clinic, or the designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.
(1) In a pharmacy, the designated person(s) must be approved by the PIC to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of HDs. The designated person(s) shall not exceed the scope of their issued license. When a designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist.
(b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.3. Types of Exposure.
In addition to the standards in USP Chapter 800, the following requirements apply to a facility that compounds HDs or crushes or splits tablets or opens capsules of antineoplastic HDs.
Any facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall ensure that all employees are aware of the types of HD exposures that may occur as referenced in USP Chapter 800. This shall be documented in SOPs and training documents.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.4. Responsibilities of Personnel Handling Hazardous Drugs.
In addition to the standards in USP Chapter 800, the PIC, designated representative-in-charge, or professional director, as applicable, shall be responsible for all activities and decisions made or approved by the designated person when the facility is compounding HDs or performing crushing or splitting tablets or opening capsules of antineoplastic HDs.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.5. Facilities and Engineering Controls.
In addition to the standards in USP Chapter 800, the following requirements apply to any facility where compounding of HDs is performed.
(a) When containment primary engineering controls (C-PECs) used for nonsterile and sterile HDs are placed in the same room, biannual certification shall document that the room can continuously maintain an ISO 7 classification throughout the nonsterile compounding activity. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.

(b) A biological-safety cabinet as defined in USP Chapter 800 Class II Type A1 shall not be used for sterile compounding of a volatile HD.
(c) Where there is a pass-through in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking by January 1, 2027.
(d) On or after January 1, 2028, prior to installing a new pass-through, a facility shall consider the use of a HEPA purge type pass-through. Documentation shall be maintained showing compliance with this requirement if such a pass-through is not used.
(e) Where sterile hazardous compounding is performed, facility room pressure monitoring equipment shall be placed consistent with CETA's Certification Guide for Sterile Compounding Facilities (CAG-003, Revised October 2022), which is hereby incorporated by reference. SOPs shall address corrective and remedial actions in the event of pressure differentials excursions.
(f) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.6. Environmental Quality and Control.
In addition to the standards in USP Chapter 800, the premises shall consider environmental wipe sampling. SOPs shall describe the consideration of and provisions for environmental wipe sampling for HD surface residue. Nothing in this section is intended to require the use of environmental wipe sampling.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.7. Personal Protective Equipment (PPE).
In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.
(a) Outer gloves used for HD compounding shall be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC, or contained in a sealable bag for discarding outside the C-PEC as established in USP 800, Section 7.6.
(b) PPE removal process shall be done in a manner to avoid transferring contamination to skin, the environment, and other surfaces. Outer PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.8. Hazard Communication Program.
In addition to the standards in USP Chapter 800, the designated person shall be involved in the premise's hazardous communication program and document the program in the SOPs and training documents.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.9. Personnel Training.
In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.
(a) Any person assigned to provide the training specified in this Article shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in

section 1737.17. Documentation must be maintained demonstrating compliance with training requirements and demonstrating competency must be maintained.
(b) All personnel responsible for compounding HDs or crushing or splitting tablets or opening capsules of antineoplastic HDs who fail any aspect of ongoing evaluation and training in compounding or crushing or splitting tablets or opening capsules of antineoplastic HDs shall not compound HDs or perform crushing or splitting tablets or opening capsules of antineoplastic HDs until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs. Any failure in personnel competency shall comply with the provisions of sections 1735.2(c) or 1736.2(d), as applicable.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.10. Receiving.
In addition to the standards in USP Chapter 800, all HD APIs and antineoplastic HDs shall be transported by the supplier in segregated impervious plastic and labeled as Hazardous Drugs on the outside of the delivery container.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.11. Labeling, Packaging, Transport and Disposal.
In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.
(a) The label for any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. A compounded HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a

juvenile detention facility shall be labeled with the patient's name, the directions for the use of the drug, and the date of issuance, but is otherwise exempt from these requirements.
(b) All compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs on the outside of the container, unless the label is visible through the outer container.
(c) When furnishing a compounded antineoplastic HD for administration within a health care facility licensed pursuant to Health and Safety Code section 1250, the HD shall be placed in a plastic container and labeled as a hazardous drug on the outside of the container or with a label that is visible through the outer container.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.12. Dispensing Final Dosage Form.
In addition to the standards in USP Chapter 800, equipment used in nonsterile HD compounding shall be dedicated for use with HDs and shall be decontaminated after each use.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.13. Compounding.
In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.
(a) If a disposable preparation mat is used for compounding a CSP it must be sterile and it must be changed immediately if a spill occurs, after each different HD preparation unless multiple preparations of the same drug or for a single patient is occurring, and at the end of the daily compounding activity.
(b) Only one HD preparation may be handled in a C-PEC at one time, unless the multiple HD preparations are of the same drug, or are multiple HD preparations for a single patient.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.14. Administering.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.

(a) When furnishing an infused compounded antineoplastic HD for administration, the facility shall attach and prime tubing and attach a CSTD when appropriate.

(b) When dispensing a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves to allow for appropriate handling and disposal of the HD. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.15. Deactivating, Decontamination, Cleaning, and Disinfecting.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.

(a) Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent manufacturer approved studies, and shall be surface compatible.

(b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in the compounding of HDs or performing crushing or splitting tablets

or opening capsules of antineoplastics HDs shall be applied through the use of wipes wetted with the appropriate solution.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.16. Spill Control.
In addition to the standards in USP Chapter 800, a facility where compounding of HDs is performed shall outline how a qualified person will be available at all times while HDs are compounded within the facility's SOPs.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.17. Documentation and Standard Operating Procedures (SOPs).
In addition to the standards in USP Chapter 800, the following requirements apply to the compounding of HDs or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.
(a) A facility shall maintain and follow written SOPs for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.
(b) A facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall have SOPs that include at least the following:
(1) Hazard communication program
(2) Occupational safety program
(3) Designation of HD areas, if compounding
(4) Receipt, if compounding
(5) Storage, if compounding
(6) Compounding, if applicable
(7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable

(8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, manipulation, administration, spill, and disposal), as applicable
(9) Deactivation, decontamination, cleaning, and disinfection
(10) Dispensing, if applicable
(11) Transport, if compounding
(12) Administering, if applicable
(13) Environmental monitoring (e.g., wipe sampling), if compounding
(14) Disposal, if compounding
(15) Spill control, if compounding
(16) Medical surveillance, if compounding
(c) The pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable, shall work with the facility's designated person to ensure SOPs are reviewed at least every 12 months and this review is documented. Documentation of compliance with the subdivision shall be maintained for three years.
(d) SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated in a written format to the staff responsible for HDs prior to implementation. All notifications of such changes and the changes shall be documented in SOPs and training documents.
(e) Failure to follow written SOPs constitutes a basis for enforcement action.
Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

Article 4.8 Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

1738. Definitions.

In addition to the terms defined in United States Pharmacopeia (USP) General Chapter 825 (USP Chapter 825), titled Radiopharmaceuticals- Preparation, Compounding, Dispensing, and Repackaging, the following definitions apply to this article

and supplement the definitions provided in USP Chapter 825 radiopharmaceutical processing activities.
(a) “Added substances” means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the term’s inactive ingredients, excipients, and pharmaceutical ingredients.
(b) “Component” means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
(c) “Designated person” means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals. Nothing in this definition prohibits the PIC from also serving as the designated person.
(d) “Processing,” “processed,” or “processing activity” means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.1. Introduction.
In addition to the standards contained in USP Chapter 825, the processing of radiopharmaceuticals that is performed by or through a licensee of the Board shall meet the requirements of this article.
(a) The use of technologies, techniques, material, and procedures not described in USP Chapter 825 shall be based upon published peer-reviewed literature or documents and meet FDA approved labeling requirements in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations, showing the technologies, techniques, material, and procedures to be equivalent or superior to those described in USP Chapter 825.

(b) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.2. Radiation Safety Considerations.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) Radiation detectors and measuring devices, and other necessary equipment, may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.
(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.
(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, or a specific radioactive materials license issued by another state or the United States Nuclear Regulatory Commission pursuant to section 32.72 of title 10 of the Code of Federal Regulations.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.3. Immediate Use of Sterile Radiopharmaceuticals.
The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.4. Personnel Qualifications, Training, and Hygiene.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or other conditions that could contaminate a sterile radiopharmaceutical or the environment shall not be allowed to enter the compounding area unless approved by the designated person. Any approvals provided by the designated person shall be documented and the record shall include the name of the individual granted approval, the approval date and time, the reason for granting approval, and the identification of the designated person making the decision.
(b) The pharmacist with direct supervision and control of personnel performing radiopharmaceutical processing shall, as defined in the facility's SOPs, demonstrate proficiency in the skills necessary to ensure the integrity, strength, quality, and labeled strength of radiopharmaceuticals.
(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:
(1) The SOPs related to compounding are identical.
(2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.

(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.
(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns in order to prevent possible contamination of the sterile radiopharmaceuticals and designated compounding area. The facility's SOPs must describe the process to be followed should the facility allow for the reuse of garb.
(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.
(f) Garb shall be donned and removed in an ante-area or immediately outside the segregated radiopharmaceutical processing area (SRPA). Donning and doffing garb shall not occur in the anteroom at the same time unless the SOPs define specific processes that must be followed to prevent contamination.
(g) Any person assigned to provide the training specified in this article shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in section 1738.14. Documentation must be maintained demonstrating compliance with training requirements and demonstrating competency must be maintained.
(h) All personnel working with radiopharmaceuticals who fail any aspect of ongoing evaluation and training in personnel qualifications shall not work with radiopharmaceuticals until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.5. Facilities and Engineering Controls.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored either manually or by a continuous recording device in the SRPA and classified areas each day that processing is performed.
(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.
(d) If an SRPA is used:
(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.
(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.
(e)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or who is under the direct supervision of an individual who possesses a current accreditation issued by CETA. The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.
(2) Certification shall be completed consistent with the provisions established in USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP <797>). CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as specified in USP Chapter 797.
(f) SOPs shall specify steps to be taken if any classified area fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures.
(g) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes when the PEC is moved, repaired, or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. SOPs must address the conditions under which

recertification must also be completed when temporarily moving or permanently relocating a PEC.
(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.
(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.6. Microbiological Air and Surface Monitoring.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) SOPs shall specify steps to be taken for processing radiopharmaceuticals when the microbiological air and surface monitoring action levels are exceeded, including the investigative and corrective actions, allowable activities, and resampling procedures.
(b) The designated person shall review and identify data trends for all sampling results. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.
(c) Environmental sampling shall be done in compliance with the Controlled Environment Testing Association's (CETA's) Certification Application Guide USP <797> Viable Environmental Monitoring for Sterile Compounding Facilities (CAG-009, Revised September 2020), which is hereby incorporated by reference.
(d) Incubators shall be cleaned, maintained, calibrated and operated in accordance with the manufacturer's specifications. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results must be reviewed and documented as described in the facility's SOPs. For incubators without specific manufacturers'

specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.7. Cleaning and Disinfecting.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.
(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.8. Assigning BUD.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) A radiopharmaceutical's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.
(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.
(c) Extension of a suggested use-by time of a conventionally manufactured kit shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.
(d) Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the pharmacy must maintain documentation of at least the following:
(1) Factors that necessitate its extension, including a full assessment of patient need for the extension.

(2) Evidence that supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.
For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.9. Documentation.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) A record of preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.
(b) A record for preparation with minor deviations or a record of compounding shall be maintained and, upon request, be produced as a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:
(1) The assigned internal identification number shall be unique for each preparation.
(2) The manufacturer, lot number, and expiration date shall be recorded for each component for radiopharmaceutical. Documenting the National Drug Code (NDC) alone does not meet this requirement.
(3) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.
(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation.
(5) When applicable, endotoxin level calculations and readings.
(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as

specified by Business and Professions Code section 4081 and 4105.
(d) Records shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record shall be maintained, for a least three years from the date the record was created, modified or relied upon, in a readily retrievable and easily readable, or rendered in an easily readable, format and include the changes to the document, identification of the individual who made the change, and the date of each change.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.10. Preparation.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) The individual responsible for preparing a nonsterile radiopharmaceutical shall:
(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Only use an area that is suitably cleaned and is uncluttered.
(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.
(b) The individual responsible for preparing a sterile radiopharmaceutical (including intravascular devices) shall:
(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.
(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) the SOPs shall at least define the circumstances that necessitate a deviation and all quality control testing requirements and limits.

(d) Equipment and supplies initially used for processing of blood components (including red blood cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next radiolabeling procedure.
(e) When processing blood components, all garb must be removed and replaced prior to initiation of the next radiolabeling procedure.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.11. Compounding.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, any other state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear Regulatory Commission pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.
(b) All API and excipient components used to compound a radiopharmaceutical shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. API and excipient components provided without this data shall not be used in a CSP. When the COA is received from a supplier, it must provide the name and address of the manufacturer.

(c) Except for sterile radiopharmaceuticals made for inhalation or ophthalmic administration, prior to releasing a sterile radiopharmaceutical made from one or more nonsterile component(s), results of bacterial endotoxin testing shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of USP Chapter 825.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.12. Dispensing.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.13. Repackaging.
In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.
(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol.
(2) The words “Caution—Radioactive Material.”
(3) The radionuclide and chemical form (generic name).
(4) Radioactivity with units at the time of calibration and the calibration time.
(b)The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol.

(2) The words “Caution—Radioactive Material.”
(3) The radionuclide and chemical form (generic name).
(4) Radioactivity with units at the time of calibration and the calibration time.
(5) Volume, or number of units (e.g., capsules), as applicable.
(6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable.
(7) Special storage and handling instructions.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301 and 4306.5, Business and Professions Code.

1738.14. Quality Assurance and Quality Control.
In addition to the standards established in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section. The facility shall have SOPs that cover and are specific to each location and manufacturer.
(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include a written procedure for any action(s) taken, in the event any radiopharmaceutical is discovered to be outside the expected standards for integrity, quality, and purity, such as a recall.
(b) The Board shall be notified in writing within 96 hours of the facility’s receipt of a complaint, excluding delivery delays, involving a radiopharmaceutical. Recalls and adverse drug experiences as defined in 21 CFR section 310.305(b) shall be reported to the Board and other agencies in compliance with relevant provisions of law.
(c) In addition to subsection (b), the pharmacist-in-charge shall initiate a review of any complaints made to the facility related to a potential quality problem with a radiopharmaceutical and any reported adverse drug experiences within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs. In the event the PIC is not

available within 72 hours, the PIC shall define in the SOPs the pharmacist who will be required to review.
(d) The SOPs shall specify the steps to be taken if any classified area fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures. This subsection shall also include actions to be taken if the compounding area or equipment is rendered unusable or in downtime situations.
(e) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to processes, facility changes, or other changes that impact the radiopharmaceutical. Such SOP changes shall be disseminated to the affected staff prior to implementation. Documentation of compliance with the subsection shall be maintained for three years.
(f) Failure to follow written SOPs constitutes a basis for enforcement action.
Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4126.9, 4127.1, 4301 and 4306.5, Business and Professions Code.

Article 5. Dangerous Drugs

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because the following classes of drugs may impair a person's ability to operate a vehicle or vessel, a pharmacist shall include a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel:

(1) Muscle relaxants.

(2) Antipsychotic drugs with central nervous system depressant effects.

(3) Antidepressants with central nervous system depressant effects.

(4) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(5) All Schedule II, III, IV and V agents with central nervous system depressant effects.

(6) Anticholinergic agents that may impair vision.

(7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel.

(b) Because the following classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall include a written label on the drug container to alert the patient about possible potentiating effects:

(1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

(5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

(6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.

1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. “Terminally ill” as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A “partially filled” prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

1746. Emergency Contraception.

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

Are you allergic to any medications?
Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.
EC use will not interfere with an established or implanted pregnancy.
If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For other options for EC, consult with your health care provider.
Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient

medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.
Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

One Tablet Regimens

Brand	***Dose***	***Ethinyl Estradiol per dose (mcg)***	***One Tablet Regimen***
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel

Two Tablet Regimens

Brand	***Dose***	***Ethinyl Estradiol per dose (mcg)***	***Two Tablet Regimen***
Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel

Brand	*Dose*	*Ethinyl Estradiol per dose (mcg)*	*Two Tablet Regimen*
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel

Oral Contraceptive Pills

Brand	*Tablets per Dose (two doses 12 hours apart*)*	*Ethinyl Estradiol per dose (mcg)*	*Levonorgestrel per dose (mg)**
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50

Brand	*Tablets per Dose (two doses 12 hours apart*)*	*Ethinyl Estradiol per dose (mcg)*	*Levonorgestrel per dose (mg)**
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Non-Prescription Drugs	*Dose*	*Timing of Administration*
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours

Non-Prescription Drugs	*Dose*	*Timing of Administration*
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;

(B) Transdermal;

(C) Vaginal;

(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;

(B) Review the self-screening answers and clarify responses if needed;

(C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended;

(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

1. Dosage;
2. Effectiveness;
3. Potential side effects;
4. Safety;
5. The importance of receiving recommended preventative health screenings;
6. That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care

facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the Food and Drug Administration (FDA). Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration- specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished

and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website. Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self- administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1. What was the first date of your last menstrual period?

2a. Have you ever taken birth control pills or used a birth control patch, ring, or shot/injection? Yes ☐ No ☐ (If no, go to question 3.)

2b. Did you ever experience a bad reaction to using hormonal birth control? Yes ☐ No ☐

2c. Are you currently using birth control pills, or a birth control patch, ring, or shot/injection? Yes ☐ No ☐

3. Have you ever been told by a medical professional not to take hormones? Yes ☐ No ☐

4. Do you smoke cigarettes? Yes ☐ No ☐

5. Do you think you might be pregnant now? Yes ☐ No ☐

6. Have you given birth within the past 6 weeks? Yes ☐ No ☐

7. Are you currently breastfeeding an infant who is less than 1 month of age? Yes ☐ No ☐

8. Do you have diabetes? Yes ☐ No ☐

9. Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness? Yes ☐ No ☐

10. Do you have high blood pressure, hypertension, or high cholesterol? Yes ☐ No ☐

11. Have you ever had a heart attack or stroke, or been told you had any heart disease? Yes ☐ No ☐

12. Have you ever had a blood clot in your leg or in your lung? Yes ☐ No ☐

13. Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung? Yes ☐ No ☐

14. Have you had bariatric surgery or stomach reduction surgery? Yes ☐ No ☐

15. Have you had recent major surgery or are you planning to have surgery in the next 4 weeks? Yes ☐ No ☐

16. Do you have or have you ever had breast cancer?

Yes ☐ No ☐

17. Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)? Yes ☐ No ☐

18. Do you have lupus, rheumatoid arthritis, or any blood disorders? Yes ☐ No ☐

19a. Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?

Yes ☐ No ☐

19b. If yes, list them here:

20a. Do you have any other medical problems or take regular medication? Yes ☐ No ☐

20b. If yes, list them here:

1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

(A) Review the patient's current tobacco use and past quit attempts.

(B) Ask the patient the following screening questions:

(i) Are you pregnant or plan to become pregnant? (If yes do not furnish and refer to an appropriate health care provider)

(ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)

(iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)

(iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)

(v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

(vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

(C) When a nicotine replacement product is furnished:

(i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.

(ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.

(D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table “Nicotine Replacement Therapy Medications for Smoking Cessation.” This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not

have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy. Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy's or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(10) Nicotine Replacement Therapy Medications for Smoking Cessation

[See the charts of Nicotine Replacement Therapy Medication for Smoking Cessation at the Board of Pharmacy website]

Note: Authority cited: Sections 4005, 4052(a)(10) and 4052.9, Business and Professions Code. Reference: Sections 4052(a)(10) and 4052.9, Business and Professions Code.

1746.3. Protocol for Pharmacists Furnishing Opioid Antagonists

A pharmacist furnishing an opioid antagonist for overdose reversalpursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) “Opioid” means naturally derived opiates as well as synthetic and semi- synthetic opioids.

(2) “Recipient” means the person to whom an opioid antagonist is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent curriculum based training program, completed in a Board recognized school of pharmacy, specific to the use of opioid antagonists for overdose reversal..

(c) Protocol for Pharmacists Furnishing Opioid Antagonists . Before providing an opioid antagonist, the pharmacist shall:

(1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist furnished.

(2) When opioid antagonist is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf---life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding the opioid antagonist furnished.

(3) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(4) Labeling: A pharmacist shall label the opioid antagonist consistent with law and regulations.

(5) At the request of the patient, a pharmacist shall notify the identified primary care provider, if any, of the product furnished or enter appropriate information in a shared patient record system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, the pharmacist shall provide the patient a written record of the drug furnished along with a recommendation for the patient to consult with an appropriate health care provider of the patient's choice.

1746.4. Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Completion of an approved immunization training program, and

(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: At the request of a patient, a pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider,

as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code, Section 120440, Health and Safety Code, and Sections 300aa – 25, Title 42, United States Code.

1746.5. Pharmacists Furnishing Travel Medications.

(a) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10)(A)(3) of the Business and

Professions Code (hereafter, “travel medications”) shall follow the requirements of this section.

(b) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), a prescription medication “not requiring a diagnosis” means a prescription medication that is either:

(1) For treatment of a condition that is recognized as both self-diagnosable and self-treatable by the CDC’s Health Information for International Travel (commonly called the Yellow Book), or

(2) For prophylaxis of a condition.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization training program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(2) Completion of a travel medicine training program, which must consist of at least 10 hours of training and cover each element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012), hereby incorporated by reference,

(3) Completion of the CDC Yellow Fever Vaccine Course, and

(4) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medications, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of the patient’s travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board’s website.

(f) Notifications: The pharmacist shall notify the patient’s primary care provider of any drugs or devices furnished to the patient within 14 days of the date of furnishing, or enter the

appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a written document that reflects the clinical assessment and travel medication plan.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the Board, provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(A) HIV preexposure and postexposure prophylaxis pharmacology.

(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(D) Patient referral resources and supplemental resources for pharmacists.

(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).

(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation of training maintained pursuant to this subdivision must be made available upon request of the board.

(c) For the purposes of this section, documentation of preexposure prophylaxis furnished and services provided shall be maintained in patient records, in the record system maintained by the pharmacy, for a minimum of three years from the date when the preexposure prophylaxis was furnished. Such records shall be made available upon request of the Board, consistent with the provisions of Business and Professions Code sections 4081 and 4105.

Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, 4052.03, 4081 and 4105, Business and Professions Code; Section 120972, Health and Safety Code.

Article 6. Fees

1749. Fee Schedule.

The application, renewal, penalties, and other fees, unless otherwise specified, are hereby fixed as follows:

(a) The fee for the issuance of any pharmacy license, including a remote dispensing site pharmacy license, is five hundred seventy dollars ($570). The fee for the annual renewal of any pharmacy license, including a remote dispensing site pharmacy license, is nine hundred and thirty dollars ($930). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of any temporary pharmacy license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license is one hundred ninety-five dollars ($195). The fee for the biennial renewal of a pharmacy technician license is one hundred fifty dollars ($150). The penalty for failure to renew is seventy-five dollars ($75).

(d) The application fee for examination as a pharmacist is two hundred eighty-five dollars ($285).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is two hundred and fifteen dollars ($215).

(2) The application fee for an advanced practice pharmacist license is three hundred dollars ($300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is five hundred five dollars ($505). The penalty fee for failure to renew is one hundred fifty dollars ($150).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance of a wholesaler or third-party logistics provider license is eight hundred twenty dollars ($820). The fee for the annual renewal of a wholesaler or third-party logistics provide license is eight hundred twenty dollars ($820). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary wholesaler or third-party logistics provider license is seven hundred fifteen dollars ($715).

(i) The fee for the issuance of a hypodermic license is two hundred forty dollars ($240). The fee for the annual renewal of a hypodermic needle license is two hundred eighty dollars ($280). The penalty for failure to renew is one hundred forty dollars ($140).

(j) The fee for the issuance of a designated representative license pursuant to Section 4053 of the Business and Professions Code, a designated representative-3PL license pursuant to Section 4053.1 of the Business and Professions Code, or a designated representative-reverse distributor license pursuant to Section 4053.2 of the Business and Professions Code, is two hundred ten dollars ($210). The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or a designated representative-reverse distributor is three hundred dollars ($300). The penalty for failure to renew is one hundred fifty dollars ($150).

(k) The application fee for the application or renewal of a license as a nonresident wholesaler or nonresident third-party logistics provider is eight hundred twenty dollars ($820). The fee for the annual renewal of a nonresident wholesaler or nonresident third-party logistics provider is eight hundred twenty dollars ($820). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a nonresident wholesaler or nonresident third-party logistics provider temporary license is seven hundred fifteen dollars ($715).

(l) The fee for an intern pharmacist license is two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).

(m) The fee for the reissuance of any license, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred thirty dollars ($130).

(n) The fee for the reissuance of any license that has been lost or destroyed or reissued due to a name change is forty-five dollars ($45).

(o) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(p) The fee for the issuance of a clinic license is five hundred seventy dollars ($570). The fee for the annual renewal of a clinic license is three hundred sixty dollars ($360). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a nongovernmental license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is two thousand three hundred five dollars ($2,305). The fee for the annual renewal of a nongovernmental license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is one thousand eight hundred fifty-five dollars ($1,855). The penalty for failure to renew a nongovernmental license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is one hundred fifty dollars ($150). The fee for a nongovernmental temporary license to compound sterile drug preparations or a hospital satellite compounding pharmacy license temporary license is seven hundred fifteen dollars ($715).

(r) The fee for the issuance of a nonresident sterile compounding pharmacy is three thousand three hundred thirty-five dollars ($3,335). The fee for the annual renewal of nonresident sterile compounding pharmacy license is three thousand one hundred eighty dollars ($3,180). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a

temporary non-resident sterile compounding pharmacy license is seven hundred fifteen dollars ($715).

(s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer is two hundred ten dollars ($210). The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer is three hundred dollars ($300). The penalty for failure to renew is one hundred fifty dollars ($150).

(t)The fee for a veterinary food-animal drug retailer license is six hundred ten dollars ($610). The application fee for the annual renewal for a veterinary food-animal drug retailer is four hundred sixty dollars ($460). The fee for a veterinary food-animal drug retailer temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred fifty dollars ($150).

(u) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

(v) The fee for the issuance of a centralized hospital packaging pharmacy license is one thousand one hundred fifty dollars ($1,150). The fee for the annual renewal of a centralized hospital packaging pharmacy license is one thousand one hundred twenty five dollars ($1,125). The penalty for failure to renew is one hundred fifty dollars ($150).

(w) The fee for the issuance of an outsourcing facility license is three thousand one hundred eighty dollars ($3,180). The fee for the annual renewal of an outsourcing facility is one thousand eight hundred fifty-five dollars ($1,855). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for an outsourcing facility temporary license is seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license is three thousand three hundred thirty-five dollars ($3,335). The fee for the annual renewal of a nonresident outsourcing facility is three thousand one hundred eighty dollars ($3,180). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a nonresident outsourcing facility temporary license is seven hundred fifteen dollars ($715).

(y) The fee for the issuance of a correctional clinic license that is not owned by the state is five hundred seventy dollars ($570). The annual renewal application fee for a corrections clinic license is three hundred sixty dollars ($360). The penalty for failure to renew is one hundred fifty dollars ($150).
(z) The application and initial license fee for the operation of an EMSADDS is one hundred dollars ($100). The application fee for the annual renewal of an EMSADDS is one hundred dollars ($100). The penalty for failure to renew is thirty-five dollars ($35).
(aa) The application fee of a co-location clinic license is seven hundred fifty dollars ($750).
(ab) The application and initial license fee for a designated paramedic license is one hundred and forty dollars ($140). The application fee for the biennial renewal of a designated paramedic license is one hundred forty dollars ($140). The penalty for failure to renew a designated paramedic license is sixty-five dollars ($65).
Note: Authority cited: Sections 4005 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, 4120, 4127.1, 4127.2, 4127.15, 4128.2, 4129.1, 4129.2, 4129.8, 4130, 4160, 4161, 4180, 4180.5, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.

Article 7.5 Furnishing for Home Administration

1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.
Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;
(D) epinephrine HCl solution 1:10,000;
(E) diphenhydramine HCl 50mg/mL;
(F) methylprednisolone 125mg/2mL;
(G) normal saline, preserved, up to 30 mL vials;
(H) naloxone 1mg/mL 2 mL;
(I) droperidol 5mg/2mL;
(J) prochlorperazine 10mg/2mL;
(K) promethazine 25mg/mL;
(L) dextrose 25gms/50mL;
(M) glucagon 1mg/mL;
(N) insulin (human) 100 units/mL;
(O) bumetamide 0.5mg/2mL;
(P) furosemide 10mg/mL;
(Q) EMLA Cream 5 gm tube;
(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health

agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home

health agency or licensed hospice complies with provisions of section 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1753.

Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

Article 8. Prohibitions and Discipline

1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code sections 11400, et seq.) the Board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 4/2024), which are hereby incorporated by reference. Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the Board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Sections 315, 315.2, 315.4, 4314 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 4300-4314, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

1761. Erroneous or Uncertain Prescriptions.

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know

that said prescription was not issued for a legitimate medical purpose.
Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 11153, Health and Safety Code.

1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(c) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

1764. Unauthorized Disclosure of Prescriptions.

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the

patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.
Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4040 and 4301, Business and Professions Code.

1765. Commissions, Gratuities, and Rebates.

An unlawful commission, gratuity or rebate prescribed by this article and Business and Professions Code Section 650 includes the rendering by a pharmacist or pharmacy of consultant pharmaceutical services such as those required pursuant to Title 22, Division 5, Chapters 3 and 4 (skilled nursing facilities and intermediate care facilities) to a licensed health care facility for no cost, nominal cost, or below reasonable cost, if that pharmacist or pharmacy obtains patients, clients or customers and/or their prescription orders from that licensed facility or entity. The determination of the value of consultant pharmaceutical services rendered shall include, but not be limited to, the value of all goods and services furnished by the pharmacist or pharmacy to a licensed health care facility.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 650 and 4301, Business and Professions Code.

1766. False or Misleading Advertising.

No pharmacist or permit holder shall violate Section 17500 of the Business and Professions Code.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 651, 4301 and 17500, Business and Professions Code.

1768. Denial of Application--Reapplication.

(a) Where the board has denied an application for a license, the earliest date on which the applicant may reapply for a license is one year after the effective date of the denial.

(b) All competent evidence of rehabilitation presented will be considered upon a reapplication. The board shall use the criteria

listed in section 1769 when considering evidence of rehabilitation.
Authority cited: Section 4005, Business and Professions Code. Reference: Sections 480, 486 and 489, Business and Professions Code.

1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant. If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

(c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

1770. Substantial Relationship Criteria.

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

Authority cited: Sections 481, 4005, Business and Professions Code. Reference: Sections 4300, 4309 and 4301, Business and Professions Code.

1771. Posting of Notice of Suspension.

Any holder of a pharmacy permit whose permit is suspended shall post a notice provided by the Board of the Board's suspension order in a location conspicuous to the public. Such notice shall remain posted during the entire period of actual suspension. Failure to post the notice of suspension as required herein shall be a ground for further disciplinary action.

Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005, Business and Professions Code.

1772. Disciplinary Condition of Suspension.

Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of licensure suspension shall not enter any pharmacy prescription area or engage in any pharmacy-related service.

Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4300, Business and Professions Code.

1773. Disciplinary Conditions of Probation of Pharmacist.

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

(1) Obey all laws and regulations substantially related to the practice of Pharmacy;

(2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;

(3) Submit to peer review if deemed necessary by the Board;

(4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;

(5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.

(6) Not supervise any registered interns nor perform any of the duties of a preceptor;

(7) The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.

(b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;

(1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;

(2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;

(3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;

(4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.

(5) Complete an ethics course that meets the requirements of section 1773.5

(c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4300, Business and Professions Code.

1773.5. Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

(a) The board will consider for approval an ethics course that at minimum satisfies the following requirements:

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The course shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.

(9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

1774. Disciplinary Conditions of Probation of Permit.

(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:

(1) Obey all laws and regulations substantially related to the practice of pharmacy;

(2) The permit, through its officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;

(3) Cooperate with the Board in its inspectional program;

(4) Post or circulate notice of conditions of probation so that they are available to all employees involved in pharmacy operations;

(5) Submit the operation of the pharmacy to peer review if deemed necessary by the Board;

(6) Provide evidence that owners or officers are knowledgeable in the laws pertaining to pharmacy if deemed necessary by the Board.

(b) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Article 9. Citations and Fines

1775. Issuing Citations.

(a) The executive officer or his/her designee may issue a citation which may contain either or both an administrative fine and an order of abatement for:

(1) A violation of the Pharmacy Law (Business and Professions Code 4000 et seq.).

(2) A violation of a regulation adopted by the board.

(3) A violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

(4) Defaulting on a United States Department of Health and Human Services education loan.

(5) A violation of other statutes or regulations for which the board may issue a citation.

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. If a hearing is not requested pursuant to this article, payment of any fine shall not constitute an admission of the violation charged.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148 and 685, Business and Professions Code; and Section 56.36, Civil Code.

1775.1. Amount of Fines.

(a) The fine for violating the Pharmacy Law or regulations adopted pursuant thereto shall not exceed the amount specified in Section 125.9 of the Business and Professions Code, except for a fine issued pursuant to Section 4067 or Section 4127.4 of the Business and Professions Code.

(b) The fine for violating the Confidentiality of Medical Information Act shall not exceed the amount specified in Section 56.36 of the Civil Code.

(c) The fine for defaulting on a United States Department of Health and Human Services education loan shall not exceed $2,500.

(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148, 685, 4067 and 4127.4, Business and Professions Code; and Section 56.36, Civil Code.

1775.2. Factors Considered.

In assessing the amount of an administrative fine, except violations of the Confidentiality of Medical Information Act and when assessing a fine pursuant to Business and Professions Code section 685, the following factors shall be considered:

(a) The gravity of the violation.

(b) The good or bad faith of the cited person or entity.

(c) The history of previous violations.

(d) Evidence that the violation was or was not willful.

(e) The extent to which the cited person or entity has cooperated with the board's investigation.

(f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.

(g) Other matters as may be appropriate.

(h) The number of violations found in the investigation.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference:

Sections 125.9, 148 and 685, Business and Professions Code; and Section 56.36, Civil Code.

1775.3. Compliance with Orders of Abatement.

(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request, from the board, an extension of time in which to complete the correction. Such a request shall be in writing and shall be made within the time set forth for abatement.

(b) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. An order of abatement shall either be personally served or mailed by certified mail. Failure to comply with an order of abatement shall constitute a ground for revocation or suspension of the license, permit, or registration. Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

1775.4. Contested Citations.

(a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)

(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request.

(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.

(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

Article 9.1. Prescription Drug Take-Back Services

1776. Prescription Drug Take-Back Services: Authorization

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board may offer, under the requirements in this article, specified prescription drug take-back services through collection

receptacles and/or mail back envelopes or packages to provide options for the public to discard unwanted, unused or outdated prescription drugs. Each entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and this article.

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third-party logistics providers) who are registered with the DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-back receptacle as authorized under this article.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4026.5, and 4301, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.

1776.1. Pharmacies

(a) Pharmacies may provide take-back services to the public. Retail pharmacies and hospital/clinics with onsite pharmacies may maintain collection receptacles in their facilities. Pharmacies may offer drug take-back services as specified in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).

(b) There are multiple federal, state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.

(c) For purposes of this article, prescription drugs means dangerous drugs as defined by Business and Professions Code section 4022, which includes controlled substances. Controlled substances may be commingled in collection receptacles or mail back envelopes or packages with other dangerous drugs.

(d) Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer, they are not to be removed, counted, sorted or otherwise individually handled.

(e) The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(f) Prescription drugs that are eligible for collection as part of drug take-back services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected as part of a pharmacy's drug take-back service.

(g) As part of its drug take-back services, a pharmacy shall not:

(1) Review, accept, count, sort, or otherwise individually handle any prescription drugs from consumers.

(2) Accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity.

(3) Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock.

(h) A pharmacy must be registered with the federal DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.

(i) Any pharmacy that maintains a drug take-back collection receptacle as authorized in this article shall notify the board in writing within 30 days of establishing the collection program. Additionally:

(1) Any pharmacy that ceases to maintain a drug take-back collection receptacle shall notify the board in writing within 30 days.

(2) Any pharmacy maintaining a collection receptacle shall disclose to the board that it provides such services annually at

the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.

(3) Any tampering with a collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days.

(4) Any tampering, damage or theft of a removed liner shall be reported to the board in writing within 14 days.

(j) If the pharmacy ceases to maintain a registered collection receptacle, the pharmacy must notify the DEA within 30 days.

(k) A pharmacy shall not provide take-back services to consumers if, in the professional judgment of the pharmacist-in-charge, the pharmacy cannot comply with the provisions of this article or the DEA rules.

(l) A pharmacy shall not provide take-back services to consumers if the pharmacy or the pharmacist-in-charge is on probation with the board, and, if the pharmacy had previously provided take-back services, the pharmacist-in-charge shall notify the board and the DEA as required in subsections (i) and (j), above.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005 and 4022, Business and Professions Code and Sections 1301.71, 1317.30, 1317.40, Title 21 Code of Federal Regulations.

1776.2. Pharmacies Offering Mail Back Envelope or Package Services

(a) Pharmacies that provide prescription drug take-back services may do so by providing preaddressed mailing envelopes or packages to allow a consumer to return prescription drugs to an authorized DEA destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the DEA as a collector. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed for delivery to facilities that comply with this section.

(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The

exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.

(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and instructions for users that indicate the process to mail back drugs.

(e) A pharmacy shall not accept any mail back packages or envelopes that contain drugs unless they are registered as a collector and have an onsite method of destruction that complies with the DEA requirements. Instead, consumers shall be directed to mail the envelopes or packages.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code and Section 1317.70, Title 21 Code of Federal Regulations.

1776.3. Collection Receptacles in Pharmacies

(a) A pharmacy may maintain a collection receptacle for the public to deposit their unwanted prescription drugs for destruction. The pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner.

(b) A pharmacy maintaining a collection receptacle must securely fasten the receptacle to a permanent structure so it cannot be removed. The receptacle shall be installed in an inside location. Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.

(d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit opening on the collection receptacle.

(e) A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A pharmacy shall not accept, count, sort or otherwise handle prescription drugs from consumers.

(f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.

(g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted or otherwise individually handled.

(h) If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately, without interruption, placed in a

rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.

(i) The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner shall be immediately, without interruption, sealed and the pharmacy employees shall record, in a log, their participation in the removal of each liner from a collection receptacle. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.

(j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than 14 days.

(k) The pharmacy shall make and keep the records specified in 1776.6.

(l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.

(m) The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, and 1317.75, Title 21 Code of Federal Regulations.

1776.4. Drug Take-Back Services in Skilled Nursing Facilities

A pharmacy may offer drug take-back services in skilled nursing facilities licensed under Health and Safety Code section 1250(c) as authorized by this article.

(a) Skilled nursing facility employees or person lawfully entitled to dispose of the resident decedent's property may dispose of unwanted or unused prescription drugs by using mail back envelopes or packages. The pharmacy shall require skilled nursing facility employees to keep records noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.

(b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:

(1) Be registered and maintain registration with the DEA as a collector.

(2) Notify the board in writing within 30 days of establishing a collection receptacle.

(3) Notify the board in writing within 30 days when they cease to maintain the collection receptacle.

(4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.

(5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.

(6) List all collection receptacles it maintains annually at the time of renewal of the pharmacy license.

(d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

(e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed. The collection

receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.

(g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.

(1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled.

(2) If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.

(h) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing and discourage removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number.

(i) The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(j) Once deposited, the prescription drugs shall not be counted, sorted or otherwise individually handled.

(k) The installation, removal, transfer and storage of inner liners shall be performed only by:

(1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or

(2) By or under the supervision of two employees of the authorized collector pharmacy.

(l) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.40, 1317.60, 1317.75, 1317.80, and 1317.95, Title 21 Code of Federal Regulations.

1776.5. Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's

authorized collection location. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not open, survey, or otherwise analyze the contents of inner liners. All liners shall be destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.

(c) If a reverse distributor picks up the sealed inner liners from the collector's authorized location, at least two employees of the reverse distributor shall be present. If the sealed inner liners are delivered to the reverse distributor via common or contract carrier, at least one employee of the reverse distributor shall accept the receipt of the inner liners at the reverse distributor's registered location.

(d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

(e) For each sealed liner or mail back envelopes or packages received pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes or packages, including the:

(1) Date of acquisition;

(2) Number and the size (e.g., five 10-gallon liners, etc.);

(3) Unique Identification number of each liner or envelope/package;

(4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;

(5) The date, place and method of destruction;

(6) Number of packages and inner liners received;

(7) Number of packages and inner liners destroyed;

(8) The name and signature of the two employees of the registrant that witnessed the destruction.

(e) For liners only, the information specified in subsection (e)(1)-(8) above shall be created at the time of receipt and at the time of destruction.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, 1317.55, and 1317.95, Title 21 Code of Federal Regulations.

1776.6. Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from consumers shall maintain the records required by this article for three years.

(a) For pharmacies maintaining collection receptacles, the pharmacy shall make and keep the following records for each liner:

(1) Date each unused liner is acquired, its unique identification number and size (e.g., 5 gallon, 10 gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.

(2) Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.

(3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing.

(4) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of

each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.

(5) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique Identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading).

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1304.22, Title 21 Code of Federal Regulations

Article 10. Dangerous Drug Distributors

1780. Minimum Standards for Wholesalers and Third-Party Logistics Providers.

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the standards set forth in the latest edition of the United States Pharmacopeia.

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the premises shall be well-lighted.

(d) All materials must be examined upon receipt and before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets the standards set forth in the latest edition of the United States Pharmacopeia.

(f) Policies and procedures must be written and made available upon request by the board.

(1) Each wholesaler and third-party logistics provider shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Each wholesaler and third-party logistics provider shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify under penalty of perjury that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161, 4161.5, 4304, and 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.

In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.

(a) Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.

(b) Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

(c) Dangerous drugs, legend drugs or extra label use drugs returned to a veterinary food-animal drug retailer from a client shall be treated as damaged or outdated prescription drugs and stored in the quarantine area specified in section 1780(e)(1). Returned drugs may not be returned to stock, or dispensed, distributed or resold.

(d) A pharmacist or person issued a permit under Business and Professions Code section 4053 (hereafter called a vet retailer designated representative) may dispense drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian. Only a pharmacist or the vet retailer designated representative may receive an oral order for a veterinary food-animal drug from the veterinarian. A written copy of the oral prescription shall be sent or electronically transmitted to the prescribing veterinarian within 72 hours.

(e) When a vet retailer designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.

(f) Whenever a vet retailer designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.

(g) Refilling a veterinarian's prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

(h) Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

(1) Active ingredients or the generic names(s) of the drug

(2) Manufacturer of the drug

(3) Strength of the drug dispensed

(4) Quantity of the drug dispensed

(5) Name of the client

(6) Species of food-producing animals for which the drug is prescribed

(7) Condition for which the drug is prescribed

(8) Directions for use

(9) Withdrawal time

(10) Cautionary statements, if any

(11) Name of the veterinarian prescriber

(12) Date dispensed

(13) Name and address of the veterinary food-animal drug retailer

(14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)

(15) Manufacturer's expiration date

(i) A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot

number, date of shipment and the name of the pharmacist or vet retailer designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

(j) If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers),. If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

(k) Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

(l) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

(m) Training of Vet Retailer Designated representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

1781. Pharmacist or Designated Representative on Premises and In Control.

(a) A registered pharmacist, or a designated representative certified in accordance with Section 4053 of the Business and Professions Code, shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

(b) A designated representative-3PL, qualified in accordance with Section 4053.1 of the Business and Professions Code, shall be present and in control of a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4053, 4053.1, 4160, and 4161, Business and Professions Code.

1782. Reporting Sales of Drugs Subject to Abuse.

Each manufacturer, wholesaler, and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4164, 4165, and 4332, Business and Professions Code.

1783. Manufacturer, Wholesaler, or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, wholesaler, or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, wholesaler, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, wholesaler, or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, wholesaler, or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, wholesaler, or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, wholesaler, or and third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, wholesaler, or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, wholesaler, or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, wholesaler, or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, wholesaler, or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.
Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4025, 4043, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4163, 4165 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

1784. Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-in-Charge or Responsible Manager.

(a) Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new license is issued.

(2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party

logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete the "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 12/21) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name, license number of the premises, and the license expiration date;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C)Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;

(D)Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law.

(5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;

(C)He or she understands that all responses are subject to verification by the Board of Pharmacy; and

(D)The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and understands that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4043, 4044.5, 4045, 4053, 4053.1, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.

Article 10.1. Home Dialysis Drugs and Devices

1787. Authorization to Distribute Dialysis Drugs and Devices.

(a) Only the following dangerous drugs and devices may be distributed directly to home dialysis patients in case or full shelf package lots:

(1) Dialysate

(2) Heparin 1000u/cc

(3) Sterile Sodium Chloride 0.9% for injection

(4) Needles

(5) Syringes

(6) Dialyzers, delivery systems and their accessory equipment necessary for chronic hemodialysis.

(b) The drugs and devices specified in 1787(a) may be distributed on the basis of a written or oral order received from a licensed prescriber. The prescriber or his or her authorized employee may transmit oral orders directly to a pharmacist or designated representative.

(c) Orders are refillable during a six-month interval as ordered by the prescriber. Records of such refills shall be retained by the supplier for three years.

Authority cited: Sections 4005 and 4059, Business and Professions Code. Reference: Sections 4059, 4081 and 4332, Business and Profession Code.

1790. Assembling and Packaging.

A record of shipment or expanded invoice shall be included in the patient's shipment, and shall include the name(s) of the drugs or devices, quantities, manufacturer's name and lot number, date of shipment, and the name of the pharmacist or designated representative who supervised and was responsible for the distribution. Copies of the record shall also be distributed to the prescribing physician and retained by the supplier for three years.

Authority cited: Sections 4005 and 4059, Business and Profession Code. Reference: Sections 4059, 4081 and 4332, Business and Professions Code.

1791. Labeling.

In addition to the manufacturer's label, each case or full shelf package furnished to a home hemodialysis patient shall have affixed in a conspicuous place the name of that patient. In addition the shipment must include the following information: the patient's name and address, the name, strength, dosage size and quantity of the dangerous drugs or devices contained therein, the name of the prescriber, the name and address of the supplier, the date of assembly, and appropriate directions for use.

Authority cited: Sections 4005 and 4059, Business and Professions Code. Reference: Sections 4059, 4081 and 4332, Business and Professions Code.

1792. Receipt for Shipment.

Upon delivery of such drugs and devices, the supplier or his or her agent shall obtain the signature of the patient or his or her agent on the invoice with notations of any discrepancies, corrections or damage.

Authority cited: Sections 4005 and 4059, Business and Professions Code. Reference: Sections 4059, 4081 and 4332, Business and Professions Code.

Article 11. Ancillary Personnel

1793. Definitions.

"Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a pharmacy, but who does not perform duties restricted to a pharmacist under section 1793.1.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.1. Duties of a Pharmacist.

Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

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

(b) 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.

(c) Identify, evaluate and interpret a prescription.

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

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

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

(g) Perform all functions which require professional judgment.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.2. Duties of a Pharmacy Technician.

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

(a) removing the drug or drugs from stock;

(b) counting, pouring, or mixing pharmaceuticals;

(c) placing the product into a container;

(d) affixing the label or labels to the container;

(e) packaging and repackaging.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.3. Other Non-Licensed Pharmacy Personnel.

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise

enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

(c) A pharmacist who, exercising his or her professional judgment pursuant to subdivision (b), refuses to supervise the number of non-licensed personnel scheduled by the pharmacy, shall notify the pharmacist-in-charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the non-licensed personnel that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule.

(d) No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Sections 4005 and 4007, Business and Professions Code. Reference: Sections 4005 and 4007, Business and Professions Code.

1793.5. Pharmacy Technician Application.

The “Pharmacy Technician Application” (Form 17A-5 (Rev. 12/2021)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 114.5, 115.4, 115.5, 4005, 4115, and 4202 Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402, Business and Professions Code; and Section 11105, Penal Code.

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c)(1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(A) Knowledge and understanding of different pharmacy practice settings.

(B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall inform applicants of the criminal background check required for a pharmacy technician license per Business and Professions Code section 4202(c). An administrator or instructor shall counsel applicants about the negative impact to securing licensure if the criminal background check reveals that the applicant has committed acts that would constitute grounds for denial of licensure.

(B) Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall inform applicants that the course of training includes practical training at a pharmacy which may require the applicant to undergo drug

screening for illicit drug use. The administrator or instructor shall counsel applicants about the negative impact of a positive drug screen, including eligibility to continue the course of training and eligibility for licensure.
(C) Require students to be at least 18 years of age prior to enrolling in any course work involving practical training, such as an externship or any other training equivalent to pharmacy technician trainee placement as defined by Business and Professions Code section 4038, 4115, 4115, and 4115.5.
(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subdivision (1) above.
Note: Authority cited: Sections 4005, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

1793.65 Pharmacy Technician Certification Programs Approved by the Board.
(a) Pursuant to Business and Professions Code section 4202(a)(4), the Board approves the pharmacy technician certification program offered by:
(1) The Pharmacy Technician Certification Board, and
(2) The National Healthcareer Association.
(b) Approval of these programs is valid through June 30, 2026.
Note: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.
(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of

the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.8. Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist. Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052.1 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Authority cited: Section 4005 and 4115, Business and Professions Code. Reference: Section 4005, 4052.1 and 4115 Business and Professions Code.

HEALTH & SAFETY CODE

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1211. Clinics Sharing Office Space

(a) Notwithstanding any other law, a clinic licensed pursuant to Section 1204 may operate in shared clinic space with a clinic exempt from licensure pursuant to subdivision (b) of Section 1206 under the following conditions:

(1) Each clinic uses signage that clearly identifies which clinic is operating during the hours of operation.

(2) The licensed clinic reports the operating hours of both clinics.

(3) Each clinic maintains separate medical records.

(4) Each clinic maintains separate drug storage.

(5) Both clinics are licensed by the California State Board of Pharmacy pursuant to Section 4180.5 of the Business and Professions Code.

(b) The department may enter and inspect the shared space at any time pursuant to Section 1227 of the Health and Safety Code, including accessing records. The exempt clinic shall allow the department to access and inspect its records.

(c) The licensed clinic shall be responsible for any statutory or regulatory violations occurring on the premises.

(d) Notwithstanding the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), the department may implement, interpret, or make specific this section by means of all-facility letters, or similar instructions, without taking regulatory action.

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

1261.5. Emergency Supplies; Doses Stored in Emergency Supplies Container

(a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4119 of the Business and
Professions Code, shall be limited to 48. The State Department of Public Health may limit the number of doses of each drug available to not more than 16 doses of any separate drug dosage form in each emergency supply.

(b) Not more than four of the 48 oral form or suppository form drugs secured for storage in the emergency supplies container shall be psychotherapeutic drugs, except that the department may grant a program flexibility request to the facility to increase the number of psychotherapeutic drugs in the emergency supplies container to not more than 10 if the facility can demonstrate the necessity for an increased number of drugs based on the needs of the patient population at the facility. In addition, the four oral form or suppository form psychotherapeutic drug limit shall not apply to a special treatment program service unit distinct part, as defined in Section 1276.9. The department shall limit the number of doses of psychotherapeutic drugs available to not more than four doses in each emergency supply. Nothing in this section shall alter or diminish informed consent requirements, including, but not limited to, the requirements of Section 1418.9.

(c) Any limitations established pursuant to subdivisions (a) and (b) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs.

1261.6. Automated Drug Delivery Systems

(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 that has an automated drug delivery system provided by a pharmacy.

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

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

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

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

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

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

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.
(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.
(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.
(f) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:
(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.
(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.
(3) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.
(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.
(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug delivery system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.
(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:
(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
(2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.
(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

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

1342.74. Health Care Service Plans Coverage of HIV Preexposure and Postexposure Prophylaxis

(a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

1342.75. Health Care Service Plans Coverage of Medication-Assisted Treatment

(a) Notwithstanding any other law, a group or individual health care service plan offering an outpatient prescription drug benefit shall provide coverage for at least one medication approved by the United States Food and Drug Administration in each of the

following categories without prior authorization, step therapy, or utilization review:

(1) Medication for the reversal of opioid overdose, including a naloxone product or another opioid antagonist.

(2) Medication for the detoxification or maintenance treatment of a substance use disorder, including a daily oral buprenorphine product.

(3) A long-acting buprenorphine product.

(4) A long-acting injectable naltrexone product.

(b) This section does not prohibit a health care service plan from selecting an AB-rated generic equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code, or interchangeable biological product, as defined in Section 262(i)(3) of Title 42 of the United States Code, to meet the requirements of subdivision (a).

DIVISION 10. UNIFORM CONTROLLED SUBSTANCE ACT

CHAPTER 1. GENERAL PROVISIONS AND DEFINITIONS

11000. Designation

This division shall be known as the "California Uniform Controlled Substances Act."

11001. Definitions Govern Construction

Unless the context otherwise requires, the definitions in this chapter govern the construction of this division.

11002. Administer Defined

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his immediate needs or to the body of a research subject by any of the following:

(a) A practitioner or, in his presence, by his authorized agent.

(b) The patient or research subject at the direction and in the presence of the practitioner.

11003. Agent Defined

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

11004. Attorney General Defined

"Attorney General" means the Attorney General of the State of California.

11005. Board of Pharmacy Defined

"Board of Pharmacy" means the California State Board of Pharmacy.

11006.5. Concentrated Cannabis Defined

(a) Before January 1, 2026, "concentrated cannabis" means the separated resin, whether crude or purified, obtained from marijuana.

(b) Beginning on January 1, 2026, and until January 1, 2028, “concentrated cannabis”or “cannabis concentrate” means cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing potency, and includes extracts, oils, hash, dab, shatter, rosin, wax, and the separated resin, whether crude or purified.

(c) Beginning on January 1, 2028, the following apply:

(1) “Concentrated cannabis” or “cannabis concentrate” means cannabis or industrial hemp that has undergone a process to concentrate one or more active cannabinoids, thereby increasing potency, and includes extracts, oils, hash, dab, shatter, rosin, wax, and the separated resin, whether crude or purified.

(2) “Cannabis concentrate” does not include CBD isolate, as defined in Section 26001 of the Business and Professions Code.

11007. Controlled Substance Defined

"Controlled substance," unless otherwise specified, means a drug, substance, or immediate precursor which is listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058.

11008. Customs Broker Defined

"Customs broker" means a person in this state who is authorized to act as a broker for any of the following:

(a) A person in this state who is licensed to sell, distribute, or otherwise possess any controlled substance.

(b) A person in any other state who ships any controlled substance into this state.

(c) A person in this state or any other state who ships or transfers any controlled substance through this state.

11010. Dispense Defined

"Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

11011. Dispenser Defined

"Dispenser" means a practitioner who dispenses.

11012. Distribute Defined

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

11013. Distributor Defined

"Distributor" means a person who distributes. The term distributor also includes warehousemen handling or storing controlled substances and customs brokers.

11014. Drug Defined

"Drug" means (a) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic

Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (c) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (d) substances intended for use as a component of any article specified in subdivision (a), (b), or (c) of this section. It does not include devices or their components, parts, or accessories.

11014.5. Drug Paraphernalia Defined

(a) "Drug paraphernalia" means all equipment, products and materials of any kind which are designed for use or marketed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this division. It includes, but is not limited to:

(1) Kits designed for use or marketed for use in planting, propagating, cultivating, growing, or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.

(2) Kits designed for use or marketed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

(3) Isomerization devices designed for use or marketed for use in increasing the potency of any species of plant which is a controlled substance.

(4) Testing equipment designed for use or marketed for use in identifying, or in analyzing the strength, effectiveness, or purity of controlled substances.

(5) Scales and balances designed for use or marketed for use in weighing or measuring controlled substances.

(6) Containers and other objects designed for use or marketed for use in storing or concealing controlled substances.

(7) Hypodermic syringes, needles, and other objects designed for use or marketed for use in parenterally injecting controlled substances into the human body.

(8) Objects designed for use or marketed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:

(A) Carburetion tubes and devices.

(B) Smoking and carburetion masks.

(C) Roach clips, meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand.

(D) Miniature cocaine spoons, and cocaine vials.

(E) Chamber pipes.

(F) Carburetor pipes.

(G) Electric pipes.

(H) Air-driven pipes.

(I) Chillums.

(J) Bongs.

(K) Ice pipes or chillers.

(b) For the purposes of this section, the phrase "marketed for use" means advertising, distributing, offering for sale, displaying for sale, or selling in a manner which promotes the use of equipment, products, or materials with controlled substances.

(c) In determining whether an object is drug paraphernalia, a court or other authority may consider, in addition to all other logically relevant factors, the following:

(1) Statements by an owner or by anyone in control of the object concerning its use.

(2) Instructions, oral or written, provided with the object concerning its use for ingesting, inhaling, or otherwise introducing a controlled substance into the human body.

(3) Descriptive materials accompanying the object which explain or depict its use.

(4) National and local advertising concerning its use.

(5) The manner in which the object is displayed for sale.

(6) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products.

(7) Expert testimony concerning its use.

(d) If any provision of this section or the application thereof to any person or circumstance is held invalid, it is the intent of the Legislature that the invalidity shall not affect other provisions or applications of the section which can be given effect without the invalid provision or application and to this end the provisions of this section are severable.

11015. Federal Bureau Defined

"Federal bureau" means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

11016. Furnish Defined

"Furnish" has the same meaning as provided in Section 4048.5 of the Business and Professions Code.

11017. Manufacturer Defined

"Manufacturer" has the same meaning as provided in Section 4034 of the Business and Professions Code.

11018. Cannabis Defined

“Cannabis” means all parts of the plant Cannabis sativa Linnaeus, Cannabis indica, or Cannabis ruderalis, whether growing or not; the seeds of that plant; the resin from glandular trichomes or extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include either of the following:

(a) Industrial hemp, as defined in Section 11018.5.

(b) The weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product.

11018.1. Cannabis Products Defined

(a) “Cannabis products” means cannabis that has undergone a process whereby the plant material has been transformed into a concentrate, including, but not limited to, concentrated cannabis, or an edible or topical product containing cannabis or concentrated cannabis and other ingredients. a product containing cannabis or cannabis concentrate and includes, but is not limited to, edible, topical, and inhaled products, and products intended for use on, or consumption by, an animal.

(b) It shall be presumed that a product intended for human or animal consumption that contains or purports to contain any tetrahydrocannabinol is a cannabis product, regardless of the nature or source of the cannabinoids. This presumption may be rebutted by evidence showing that the product complies with Chapter 9 (commencing with Section 111920) of Part 5 of Division 104 and any regulations promulgated pursuant to that chapter.

11018.5. Industrial Hemp Defined

(a)(1) “Industrial hemp” or “hemp” types of the plant Cannabis sativa Linnaeus or any part of that plant with a total tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis and is limited to only agricultural products, including seeds, propagated plant material, immature or mature plants, harvested plants, mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, or any preparation that does not contain cannabinoids.

(2) Total tetrahydrocannabinol concentration includes both delta-9 tetrahydrocannabinol and tetrahydrocannabinolic acid, and shall be calculated using the following equation: Total THC concentration (mg/g) +/- the measurement of uncertainty, as defined by the Department of Food and Agriculture.

(b) Industrial hemp shall not be subject to the provisions of this division or of Division 10 (commencing with Section 26000) of the Business and Professions Code, except upon entry into the California licensed market under that division, and shall be regulated by the Department of Food and Agriculture in

accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agricultural Code, inclusive.
(c) The sale or delivery of hemp flower and hemp prerolls within the state is prohibited.

11019. Narcotic Drug Defined

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.
(b) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in subdivision (a), but not including the isoquinoline alkaloids of opium.
(c) Opium poppy and poppy straw.
(d) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.
(e) Cocaine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.
(f) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.
(g) Acetylfentanyl, the thiophene analog thereof, derivatives of either, and any salt, compound, isomer, or preparation of acetylfentanyl or the thiophene analog thereof.

11020. Opiate Defined

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Chapter 2 (commencing with Section 11053) of this division, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

11021. Opium Poppy Defined

"Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

11022. Person Defined

"Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, limited liability company, or association, or any other legal entity.

11023. Pharmacy Defined

"Pharmacy" has the same meaning as provided in Section 4035 of the Business and Professions Code.

11024. Physician, Dentist, Podiatrist, Pharmacist, and Veterinarian Defined

"Physician," "dentist," "podiatrist," "pharmacist," "veterinarian," and "optometrist" means persons who are licensed to practice their respective professions in this state.

11025. Poppy Straw Defined

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

11026. Practitioner Defined

"Practitioner" means any of the following:

(a) A physician, dentist, veterinarian, podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, or a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of

Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code.

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer, a controlled substance in the course of professional practice or research in this state.

(c) A scientific investigator, or other person licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.

11027. Prescription Defined

(a) "Prescription" means an oral order or electronic transmission prescription for a controlled substance given individually for the person(s) for whom prescribed, directly from the prescriber to the furnisher or indirectly by means of a written order of the prescriber.

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

11029. Production Defined

"Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

11029.5. Security Printer Defined

"Security printer" means a person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

11030. Ultimate User Defined

"Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

11031. Wholesaler Defined

"Wholesaler" has the same meaning as provided in Section 4038 of the Business and Professions Code.

11032. References to Narcotics, Restricted Dangerous Drugs, Marijuana as Schedule I, II, III and IV Controlled Substances

Whenever reference is made to the term "narcotics" in any provision of law outside of this division, unless otherwise expressly provided, it shall be construed to mean controlled substances classified in Schedules I and II, as defined in this division. Whenever reference is made to "restricted dangerous drugs" outside of this division, unless otherwise expressly provided, it shall be construed to mean controlled substances classified in Schedules III and IV. Whenever reference is made to the term "marijuana" in any provision of law outside of this division, unless otherwise expressly provided, it shall be construed to mean marijuana as defined in this division.

11033. Isomer Defined

As used in this division, except as otherwise defined, the term "isomer" includes optical and geometrical (diastereomeric) isomers.

CHAPTER 2. STANDARDS AND SCHEDULES

11053. Substances Included by Whatever Name Used

The controlled substances listed or to be listed in the schedules in this chapter are included by whatever official, common, usual, chemical, or trade name designated.

11054. Schedule I Controlled Substances

(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) Etoxeridine.

(24) Furethidine.

(25) Hydroxypethidine.

(26) Ketobemidone.

(27) Levomoramide.

(28) Levophenacylmorphan.
(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) Hydromorphinol.
(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-alphamethylphenethylamine; 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-alphamethylphenethylamine; "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)-5indolol; 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-5Hpyrido (1',2':1,2) azepino (5,4-b) indole; Tabernantheiboga.
(12) Lysergic acid diethylamide.
(13) 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. Because nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions 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) Fenethylline, including its salts.

(3) N-Ethylamphetamine, including its salts.

11055. Schedule II Controlled Substances

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

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

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

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Codeine.

(H) Ethylmorphine.

(I) (i) Hydrocodone.

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

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

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

(J) Hydromorphone.

(K) Metopon.

(L) Morphine.

(M) Oxycodone.

(N) Oxymorphone.
(O) Thebaine.
(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw.
(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.
(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).
(6) Cocaine, except as specified in Section 11054.
(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.
(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:
(1) Alfentanyl.
(2) Alphaprodine.
(3) Anileridine.
(4) Bezitramide.
(5) Bulk dextropropoxyphene (nondosage forms).
(6) Dihydrocodeine.
(7) Diphenoxylate.
(8) Fentanyl.
(9) Isomethadone.
(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).
(11) Levomethorphan.

(12) Levorphanol.
(13) Metazocine.
(14) Methadone.
(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
(17) Pethidine (meperidine).
(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(21) Phenazocine.
(22) Piminodine.
(23) Racemethorphan.
(24) Racemorphan.
(25) Sufentanyl.
(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Methamphetamine, its salts, isomers, and salts of its isomers.
(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.
(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.
(5) Phenmetrazine and its salts.
(6) Methylphenidate.
(7) Khat, which includes all parts of the plant classified botanically as Catha Edulis, whether growing or not, the seeds thereof, any extract from any part of the plant, and every

compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

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

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

(1) Amobarbital.

(2) Pentobarbital.

(3) Phencyclidines, including the following:

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

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

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

(4) Secobarbital.

(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or

preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

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

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

11056. Schedule III Controlled Substances

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

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

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

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

(c) Depressants. Unless specifically excepted in Section 11059 or elsewhere, or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of

the following substances having a depressant effect on the central nervous system:

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

(A) Amobarbital.

(B) Secobarbital.

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

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

(A) Amobarbital.

(B) Secobarbital.

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

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

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

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

(d) Nalorphine.

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

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

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

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

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

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

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

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

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chloromethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.
(11) Formyldienolone.
(12) 4-Hydroxy-19-nortestosterone.
(13) Mesterolone.
(14) Methandriol.
(15) Methandrostenolone.
(16) Methenolone.
(17) 17-Methyltestosterone.
(18) Methyltrienolone.
(19) Nandrolone.
(20) Norbolethone.
(21) Norethandrolone.
(22) Normethandrolone.
(23) Oxandrolone.
(24) Oxymesterone.
(25) Oxymetholone.
(26) Quinbolone.
(27) Stanolone.
(28) Stanozolol.
(29) Stenbolone.
(30) Testosterone.
(31) Trenbolone.

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

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

11057. Schedule IV Controlled Substances

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

(b) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

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

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane).

(3) Butorphanol.

(d) Depressants. Unless specifically excepted in Section 11059 or elsewhere, or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, 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) Alprazolam.

(2) Barbital.

(3) Chloral betaine.

(4) Chloral hydrate.

(5) Chlordiazepoxide.

(6) Clobazam.

(7) Clonazepam.

(8) Clorazepate.

(9) Diazepam.

(10) Estazolam.

(11) Ethchlorvynol.

(12) Ethinamate.

(13) Flunitrazepam.

(14) Flurazepam.

(15) Halazepam.

(16) Lorazepam.

(17) Mebutamate.

(18) Meprobamate.

(19) Methohexital.

(20) Methylphenobarbital (Mephobarbital).

(21) Midazolam.
(22) Nitrazepam.
(23) Oxazepam.
(24) Paraldehyde.
(25) Petrichoral.
(26) Phenobarbital.
(27) Prazepam.
(28) Quazepam.
(29) Temazepam.
(30) Triazolam.
(31) Zaleplon.
(32) Zolpidem.

(e) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers, whenever the existence of those salts, isomers, and salts of isomers is possible:

(1) Fenfluramine.

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

(1) Diethylpropion.
(2) Mazindol.
(3) Modafinil.
(4) Phentermine.
(5) Pemoline (including organometallic complexes and chelates thereof).
(6) Pipradrol.
(7) SPA ((-)-1-dimethylamino-1,2-diphenylethane).
(8) Cathine ((+)-norpseudoephedrine).

(g) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or

preparation which contains any quantity of pentazocine, including its salts.

11058. Schedule V Controlled Substances

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

(b) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(c) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) Buprenorphine.

11059. Schedule Exceptions

(a) Specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a derivative of barbituric acid or any salt thereof that are listed in the federal Table of Exempted Prescription Products and have been exempted pursuant to federal law or regulation (Section

1308.32 of Title 21 of the Code of Federal Regulations or its successors), are excepted from scheduling under subdivision (c) of Section 11056.

(b) Specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a chlordiazepoxide or phenobarbital that are listed in the federal Table of Exempted Prescription Products and have been exempted from scheduling under federal law or regulation (Section 1308.32 of Title 21 of the Code of Federal Regulations or its successors) are excepted from scheduling under subdivision (d) of Section 11057.

CHAPTER 3. REGULATION AND CONTROL

Article 1. Reporting

11100. Report of Certain Chemical: Chemicals Included; Exclusions; Penalties

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

(1) Phenyl-2-propanone.
(2) Methylamine.
(3) Ethylamine.
(4) D-lysergic acid.
(5) Ergotamine tartrate.
(6) Diethyl malonate.
(7) Malonic acid.
(8) Ethyl malonate.
(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.

(14) Anthranilic acid.
(15) Morpholine.
(16) Ephedrine.
(17) Pseudoephedrine.
(18) Norpseudoephedrine.
(19) Phenylpropanolamine.
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.
(24) Thionyl chloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.
(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).
(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).
(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.
(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, “proper identification” for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller’s permit identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; driver’s license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in

subdivision (a) to any person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to

the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

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

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) Any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United

States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

(3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or

phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) “Drug store” is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) “General merchandise store” is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) “Grocery store” is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) “Pediatric liquid” means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to

children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) “Retail distributor” means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. “Retail distributor” includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

(6) “Sale for personal use” means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). “Sale for personal use” also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

11100.05. Drug Cleanup Fine

(a) In addition to any fine or imprisonment imposed under subdivision (f) of Section 11100 or subdivision (j) of Section 11106 of the Health and Safety Code, the following drug cleanup fine shall be imposed:

(1) Ten thousand dollars ($10,000) for violations described in paragraph (1) of subdivision (f) of Section 11100.

(2) One hundred thousand dollars ($100,000) for violations described in paragraph (2) of subdivision (f) of Section 11100.

(3) Ten thousand dollars ($10,000) for violations described in subdivision (j) of Section 11106.

(b) At least once a month, all fines collected under this section shall be transferred to the State Treasury for deposit in the Clandestine Drug Lab Clean-up Account. The transmission to the State Treasury shall be carried out in the same manner as fines collected for the state by a county.

11100.1. Report of Chemicals Received from Outside State; Penalties

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that obtains from a source outside of this state any substance specified in subdivision (a) of Section 11100 shall submit a report of that transaction to the Department of Justice 21 days in advance of obtaining the substance. However, the Department of Justice may authorize the submission of reports within 72 hours, or within a timeframe and in a manner acceptable to the Department of Justice, after the actual physical obtaining of a specified substance with respect to repeated transactions between a furnisher and an obtainer involving the substances, if the Department of Justice determines that the obtainer has established a record of utilization of the substances for lawful purposes. This section does not apply to any person whose prescribing or dispensing activities are subject to the reporting requirements set forth in Section 11164; any manufacturer or wholesaler who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration of the United States Department of Justice; any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice; or any state-licensed health care facility.

(b) (1) Any person specified in subdivision (a) who does not submit a report as required by that subdivision shall be

punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both that fine and imprisonment.

(2) Any person specified in subdivision (a) who has been previously convicted of a violation of subdivision (a) who subsequently does not submit a report as required by subdivision (a) shall be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both that fine and imprisonment.

11101. Reporting Form Contents

The State Department of Justice shall provide a common reporting form for the substances in Section 11100 which contains at least the following information:

(a) Name of the substance.

(b) Quantity of the substance sold, transferred, or furnished.

(c) The date the substance was sold, transferred, or furnished.

(d) The name and address of the person buying or receiving such substance.

(e) The name and address of the manufacturer, wholesaler, retailer, or other person selling, transferring, or furnishing such substance.

11102. Adoption of Necessary Regulations

The Department of Justice may adopt all regulations necessary to carry out the provisions of this part.

11103. Report of Theft, Loss, or Shipping Discrepancy

The theft or loss of any substance regulated pursuant to Section 11100 discovered by any permittee or any person regulated by the provisions of this chapter shall be reported in writing to the Department of Justice within three days after the discovery. Any difference between the quantity of any substance regulated pursuant to Section 11100 received and the quantity shipped shall be reported in writing to the Department of Justice within three days of the receipt of actual knowledge of the discrepancy.

Any report made pursuant to this section shall also include the name of the common carrier or person who transports the substance and date of shipment of the substance.

11104. Providing Chemical for Illicit Manufacturing: Evasion of Reporting Requirements; Penalties

(a) Any manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes any of the substances listed in subdivision (a) of Section 11100 with knowledge or the intent that the recipient will use the substance to unlawfully manufacture a controlled substance is guilty of a felony.

(b) Any manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, or any chemical substance specified in Section 11107.1, with knowledge that the recipient will use the goods or chemical substance to unlawfully manufacture a controlled substance, is guilty of a misdemeanor.

(c) Any person who receives or distributes any substance listed in subdivision (a) of Section 11100, or any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, or any chemical substance specified in Section 11107.1, with the intent of causing the evasion of the recordkeeping or reporting requirements of this article, is guilty of a misdemeanor.

11104.5. Illegal Possession of Certain Glassware or Lab Apparatus

Any person who knowingly or intentionally possesses any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, or any chemical substance specified in paragraph (36) or (37) of subdivision (a) of Section 11100, Section 11107, or Section 11107.1, with the intent to manufacture a controlled substance, is guilty of a misdemeanor.

11105. False Statement in Report

(a) It is unlawful for any person to knowingly make a false statement in connection with any report or record required under this article.

(b) (1) Any person who violates this section shall be punished by imprisonment in the state prison, or by imprisonment in the county jail not exceeding one year, or by a fine not exceeding five thousand dollars ($5,000), or by both such fine and imprisonment.

(2) Any person who has been previously convicted of violating this section and who subsequently violates this section shall be punished by imprisonment in the state prison for two, three, or four years, or by a fine not exceeding one hundred thousand dollars ($100,000), or by both such fine and imprisonment.

11106. Permit for Providing Chemicals; Process; Discipline; Renewal and Fees

(a) (1) (A) Any manufacturer, wholesaler, retailer, or any other person or entity in this state that sells, transfers, or otherwise furnishes any substance specified in subdivision (a) of Section 11100 to a person or business entity in this state or any other state or who obtains from a source outside of the state any substance specified in subdivision (a) of Section 11100 shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice. For any substance added to the list set forth in subdivision (a) of Section 11100 on or after January 1, 2002, the Department of Justice may postpone the effective date of the requirement for a permit for a period not to exceed six months from the listing date of the substance.

(B) An intracompany transfer does not require a permit if the transferor is a permittee. Transfers between company partners or between a company and an analytical laboratory do not require a permit if the transferor is a permittee and a report as to the nature and extent of the transfer is made to the Department of Justice pursuant to Section 11100 or 11100.1.

(C) This paragraph shall not apply to any manufacturer, wholesaler, or wholesale distributor who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration of the United States Department of Justice; any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian; any state-licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food-animal drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(D) This paragraph shall not apply to the sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person or entity for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.

(3) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1).

(b) (1) The department shall provide application forms, which are to be completed under penalty of perjury, in order to obtain information relating to the identity of any applicant applying for a permit, including, but not limited to, the business name of the applicant or the individual name, and if a corporate entity, the names of its board of directors, the business in which the applicant is engaged, the business address of the applicant, a full description of any substance to be sold, transferred, or otherwise furnished or to be obtained, the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100, the training, experience, or education relating to this use, and any additional information requested by the department relating to possible grounds for denial as set forth in this section, or by applicable regulations adopted by the department.

(2) The requirement for the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100 does not require applicants or permittees to reveal their chemical processes that are typically considered trade secrets and proprietary business information.

(c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.

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

(1) Materially falsifying an application for a permit or an application for the renewal of a permit.

(2) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, is or has been convicted of a misdemeanor or felony relating to any of the substances listed under subdivision

(a) of Section 11100, any misdemeanor drug-related offense, or any felony under the laws of this state or the United States.

(3) Failure to maintain effective controls against the diversion of precursors to unauthorized persons or entities.

(4) Failure to comply with this article or any regulations of the department adopted thereunder.

(5) Failure to provide the department, or any duly authorized federal or state official, with access to any place for which a permit has been issued, or for which an application for a permit has been submitted, in the course of conducting a site investigation, inspection, or audit; or failure to promptly produce for the official conducting the site investigation, inspection, or audit any book, record, or document requested by the official.

(6) Failure to provide adequate documentation of a legitimate business purpose involving the applicant's or permittee's use of any substance listed in subdivision (a) of Section 11100.

(7) Commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions, or duties of a permitholder.

(8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.

(e) Notwithstanding any other provision of law, an investigation of an individual applicant's qualifications, or the qualifications of an applicant's owner, manager, agent, representative, or employee who has direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for a permit may include review of his or her summary criminal history information pursuant to Sections 11105 and 13300 of the Penal Code, including, but not limited to, records of convictions, regardless of whether those convictions have been expunged

pursuant to Section 1203.4 of the Penal Code, and any arrests pending adjudication.

(f) The department may retain jurisdiction of a canceled or expired permit in order to proceed with any investigation or disciplinary action relating to a permittee.

(g) The department may grant permits on forms prescribed by it, which shall be effective for not more than one year from the date of issuance and which shall not be transferable. Applications and permits shall be uniform throughout the state, on forms prescribed by the department.

(h) Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department.

(i) A permit granted pursuant to this article may be renewed one year from the date of issuance, and annually thereafter, following the timely filing of a complete renewal application with all supporting documents, the payment of a permit renewal fee not to exceed the application processing costs of the department, and a review of the application by the department.

(j) Selling, transferring, or otherwise furnishing or obtaining any substance specified in subdivision (a) of Section 11100 without a permit is a misdemeanor or a felony.

(k) (1) No person under 18 years of age shall be eligible for a permit under this section.

(2) No business for which a permit has been issued shall employ a person under 18 years of age in the capacity of a manager, agent, or representative.

(l) (1) An applicant, or an applicant's employees who have direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for an initial permit shall submit with the application one set of 10-print fingerprints for each individual acting in the capacity of an owner, manager, agent, or representative for the applicant, unless the applicant's employees are exempted from this requirement by the Department of Justice. These exemptions may only be obtained upon the written request of the applicant.

(2) In the event of subsequent changes in ownership, management, or employment, the permittee shall notify the department in writing within 15 calendar days of the changes, and shall submit one set of 10-print fingerprints for each individual not previously fingerprinted under this section.

11106.5. Order Suspending or Imposing Permit Restrictions

(a) The Department of Justice, or an administrative law judge sitting alone as provided in subdivision (h), may upon petition issue an interim order suspending any permittee or imposing permit restrictions. The petition shall include affidavits that demonstrate, to the satisfaction of the department, both of the following:

(1) The permittee has engaged in acts or omissions constituting a violation of this code or has been convicted of a crime substantially related to the permitted activity.

(2) Permitting the permittee to operate, or to continue to operate without restrictions, would endanger the public health, safety, or welfare.

(b) No interim order provided for in this section shall be issued without notice to the permittee, unless it appears from the petition and supporting documents that serious injury would result to the public before the matter could be heard on notice.

(c) Except as provided in subdivision (b), the permittee shall be given at least 15 days' notice of the hearing on the petition for an interim order. The notice shall include documents submitted to the department in support of the petition. If the order was initially issued without notice as provided in subdivision (b), the permittee shall be entitled to a hearing on the petition within 20 days of the issuance of the interim order without notice. The permittee shall be given notice of the hearing within two days after issuance of the initial interim order, and shall receive all documents in support of the petition. The failure of the department to provide a hearing within 20 days following issuance of the interim order without notice, unless the permittee waives his or her right to the hearing, shall result in the dissolution of the interim order by operation of law.

(d) At the hearing on the petition for an interim order, the permittee may do the following:

(1) Be represented by counsel.

(2) Have a record made of the proceedings, copies of which shall be available to the permittee upon payment of costs computed in accordance with the provisions for transcript costs for judicial review contained in Section 11523 of the Government Code.

(3) Present affidavits and other documentary evidence.

(4) Present oral argument.

(e) The department, or an administrative law judge sitting alone as provided in subdivision (h), shall issue a decision on the petition for interim order within five business days following submission of the matter. The standard of proof required to obtain an interim order pursuant to this section shall be a preponderance of the evidence standard. If the interim order was previously issued without notice, the department shall determine whether the order shall remain in effect, be dissolved, or be modified.

(f) The department shall file an accusation within 15 days of the issuance of an interim order. In the case of an interim order issued without notice, the time shall run from the date of the order issued after the noticed hearing. If the permittee files a notice of defense, the hearing shall be held within 30 days of the agency's receipt of the notice of defense. A decision shall be rendered on the accusation no later than 30 days after submission of the matter. Failure to comply with any of the requirements in this subdivision shall dissolve the interim order by operation of law.

(g) Interim orders shall be subject to judicial review pursuant to Section 1094.5 of the Code of Civil Procedure and shall be heard only in the superior court in and for the County of Sacramento, San Francisco, Los Angeles, or San Diego. The review of an interim order shall be limited to a determination of whether the department abused its discretion in the issuance of the interim order. Abuse of discretion is established if the respondent department has not proceeded in the manner required by law, or

if the court determines that the interim order is not supported by substantial evidence in light of the whole record.

(h) The department may, in its sole discretion, delegate the hearing on any petition for an interim order to an administrative law judge in the Office of Administrative Hearings. If the department hears the noticed petition itself, an administrative law judge shall preside at the hearing, rule on the admission and exclusion of evidence, and advise the department on matters of law. The department shall exercise all other powers relating to the conduct of the hearing, but may delegate any or all of them to the administrative law judge. When the petition has been delegated to an administrative law judge, he or she shall sit alone and exercise all of the powers of the department relating to the conduct of the hearing. A decision issued by an administrative law judge sitting alone shall be final when it is filed with the department. If the administrative law judge issues an interim order without notice, he or she shall preside at the noticed hearing, unless unavailable, in which case another administrative law judge may hear the matter. The decision of the administrative law judge sitting alone on the petition for an interim order is final, subject only to judicial review in accordance with subdivision (g).

(i) (1) Failure to comply with an interim order issued pursuant to subdivision (a) or (b) shall constitute a separate cause for disciplinary action against any permittee, and may be heard at, and as a part of, the noticed hearing provided for in subdivision (f). Allegations of noncompliance with the interim order may be filed at any time prior to the rendering of a decision on the accusation. Violation of the interim order is established upon proof that the permittee was on notice of the interim order and its terms, and that the order was in effect at the time of the violation. The finding of a violation of an interim order made at the hearing on the accusation shall be reviewed as a part of any review of a final decision of the department.

(2) If the interim order issued by the department provides for anything less than a complete suspension of the permittee and the permittee violates the interim order prior to the hearing on

the accusation provided for in subdivision (f), the department may, upon notice to the permittee and proof of violation, modify or expand the interim order.

(j) A plea or verdict of guilty or a conviction after a plea of nolo contendere is deemed to be a conviction within the meaning of this section. A certified record of the conviction shall be conclusive evidence of the fact that the conviction occurred. The department may take action under this section notwithstanding the fact that an appeal of the conviction may be taken.

(k) The interim orders provided for by this section shall be in addition to, and not a limitation on, the authority to seek injunctive relief provided in any other provision of law.

11106.7. System for DOJ Citations to Permittees; Order of Abatement or Order to Pay Fine; System Requirements

(a) The Department of Justice may establish, by regulation, a system for the issuance to a permittee of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the Department of Justice, if the permittee is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(b) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars ($2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the permittee, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the permittee that if the permittee desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the department within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the permittee may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied and the order of abatement. However, the permittee does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a permittee to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action being taken by the department. If a citation is not contested and a fine is not paid, the full amount of the assessed fine shall be added to the renewal of the permit. A permit shall not be renewed without payment of the renewal fee and fine.

(c) The system may contain the following provisions:

(1) A citation may be issued without the assessment of an administrative fine.

(2) Assessment of administrative fines may be limited to only particular violations of the law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the General Fund.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a permit if grounds for that suspension or revocation exist.

11107. Sale of Laboratory Items: Required Procedures and Records; Penalties for Violation

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells to any person or entity in this state or any other state, any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, where the value of the goods sold in the transaction exceeds one hundred dollars ($100) shall do the following:

(1) Notwithstanding any other law, in any face-to-face or will-call sale, the seller shall prepare a bill of sale which identifies the date of sale, cost of product, method of payment, specific items and quantities purchased, and the proper purchaser identification information, all of which shall be entered onto the bill of sale or a legible copy of the bill of sale, and shall also affix on the bill of sale his or her signature as witness to the purchase and identification of the purchaser.

(A) For the purposes of this section, “proper purchaser identification” includes a valid motor vehicle operator’s license or other official and valid state-issued identification of the purchaser that contains a photograph of the purchaser, and includes the residential or mailing address of the purchaser, other than a post office box number, the motor vehicle license number of the motor vehicle used by the purchaser at the time of purchase, a description of how the substance is to be used, and the signature of the purchaser.

(B) The seller shall retain the original bill of sale containing the purchaser identification information for five years in a readily presentable manner, and present the bill of sale containing the purchaser identification information upon demand by any law enforcement officer or authorized representative of the Attorney General. Copies of these bills of sale obtained by representatives of the Attorney General shall be maintained by the Department of Justice for a period of not less than five years.

(2) (A) Notwithstanding any other law, in all sales other than face-to-face or will-call sales the seller shall maintain for a period of five years the following sales information: the name and address of the purchaser, date of sale, product description, cost of product, method of payment, method of delivery, delivery address, and valid identifying information.

(B) For the purposes of this paragraph, “valid identifying information” includes two or more of the following: federal tax identification number; resale tax identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; motor vehicle operator’s license; or other identification issued by a state.

(C) The seller shall, upon the request of any law enforcement officer or any authorized representative of the Attorney General, produce a report or record of sale containing the information in a readily presentable manner.

(D) If a common carrier is used, the seller shall maintain a manifest regarding the delivery in a readily presentable manner and for a period of five years.

(b) This section shall not apply to any wholesaler who is licensed by the California State Board of Pharmacy and registered with the federal Drug Enforcement Administration of the United States Department of Justice and who sells laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian.

(c) A violation of this section is a misdemeanor.

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

(1) “Laboratory glassware” includes, but is not limited to, condensers, flasks, separatory funnels, and beakers.

(2) “Apparatus” includes, but is not limited to, heating mantles, ring stands, and rheostats.

(3) “Chemical reagent” means a chemical that reacts chemically with one or more precursors, but does not become part of the finished product.

(4) “Chemical solvent” means a chemical that does not react chemically with a precursor or reagent and does not become part of the finished product. A “chemical solvent” helps other chemicals mix, cools chemical reactions, and cleans the finished product.

11107.1. Requirements When Selling Specified Chemicals; Violation as Misdemeanor

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells to any person or entity in this state or any other state any quantity of sodium cyanide, potassium cyanide, cyclohexanone, bromobenzene, magnesium turnings, mercuric chloride, sodium metal, lead acetate, palladium black, hydrogen chloride gas, trichlorofluoromethane (fluorotrichloromethane), dichlorodifluoromethane, 1,1,2-trichloro-1,2,2-trifluoroethane (trichlorotrifluoroethane), sodium acetate, or acetic anhydride shall do the following:

(1) (A) Notwithstanding any other provision of law, in any face-to-face or will-call sale, the seller shall prepare a bill of sale which identifies the date of sale, cost of sale, method of payment, the specific items and quantities purchased and the proper purchaser identification information, all of which shall be entered onto the bill of sale or a legible copy of the bill of sale, and shall also affix on the bill of sale his or her signature as witness to the purchase and identification of the purchaser.

(B) For the purposes of this paragraph, "proper purchaser identification" includes a valid driver's license or other official and valid state-issued identification of the purchaser that contains a photograph of the purchaser, and includes the residential or mailing address of the purchaser, other than a post office box number, the motor vehicle license number of the motor vehicle used by the purchaser at the time of purchase, a description of how the substance is to be used, the Environmental Protection Agency certification number or resale tax identification number assigned to the individual or business entity for which the individual is purchasing any chlorofluorocarbon product, and the signature of the purchaser.

(C) The seller shall retain the original bill of sale containing the purchaser identification information for five years in a readily presentable manner, and present the bill of sale containing the purchaser identification information upon demand by any law enforcement officer or authorized representative of the Attorney General. Copies of these bills of sale obtained by representatives of the Attorney General shall be maintained by the Department of Justice for a period of not less than five years.

(2) (A) Notwithstanding any other law, in all sales other than face-to-face or will-call sales the seller shall maintain for a period of five years the following sales information: the name and address of the purchaser, date of sale, product description, cost of product, method of payment, method of delivery, delivery address, and valid identifying information.

(B) For the purposes of this paragraph, "valid identifying information" includes two or more of the following: federal tax identification number; resale tax identification number; city or

county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; driver's license; or other identification issued by a state.

(C) The seller shall, upon the request of any law enforcement officer or any authorized representative of the Attorney General, produce a report or record of sale containing the information in a readily presentable manner.

(D) If a common carrier is used, the seller shall maintain a manifest regarding the delivery in a readily presentable manner for a period of five years.

(b) Any manufacturer, wholesaler, retailer, or other person or entity in this state that purchases any item listed in subdivision (a) of Section 11107.1 shall do the following:

(1) Provide on the record of purchase information on the source of the items purchased, the date of purchase, a description of the specific items, the quantities of each item purchased, and the cost of the items purchased.

(2) Retain the record of purchase for three years in a readily presentable manner and present the record of purchase upon demand to any law enforcement officer or authorized representative of the Attorney General.

(c) (1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or both the fine and imprisonment.

11110. Sale of Dextromethorphan Prohibited to Those Under 18 Years of Age without Prescription

(a) It shall be an infraction, punishable by a fine not exceeding two hundred fifty dollars ($250), for any person, corporation, or retail distributor to willfully and knowingly supply, deliver, or give possession of a drug, material, compound, mixture, preparation, or substance containing any quantity of dextromethorphan (the dextrorotatory isomer of 3-methoxy-N-methylmorphinan, including its salts, but not including its racemic or levorotatory forms) to a person under 18 years of age in an over-the-counter sale without a prescription.

(b) It shall be prima facie evidence of a violation of this section if the person, corporation, or retail distributor making the sale does not require and obtain bona fide evidence of majority and identity from the purchaser, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be 25 years of age or older.

(c) Proof that a person, corporation, or retail distributor, or his or her agent or employee, demanded, was shown, and acted in reasonable reliance upon, bona fide evidence of majority and identity shall be a defense to any criminal prosecution under this section. As used in this section, "bona fide evidence of majority and identity" means a document issued by a federal, state, county, or municipal government, or subdivision or agency thereof, including, but not limited to, a motor vehicle operator's license, California state identification card, identification card issued to a member of the Armed Forces, or other form of identification that bears the name, date of birth, description, and picture of the person.

(d) (1) Notwithstanding any other provision of this section, a retail clerk who fails to require and obtain proof of age from the purchaser shall not be guilty of an infraction pursuant to subdivision (a) or subject to any civil penalties.

(2) This subdivision shall not apply to a retail clerk who is a willful participant in an ongoing criminal conspiracy to violate this section.

11111. Use of Cash Register with Age-Verification Feature for OTC Sale of Dextromethorphan

A person, corporation, or retail distributor that sells or makes available products containing dextromethorphan, as defined in subdivision (a) of Section 11110, in an over-the-counter sale without a prescription shall, if feasible, use a cash register that is equipped with an age-verification feature to monitor age-restricted items. The cash register shall be programmed to direct the retail clerk making the sale to request bona fide evidence of majority and identity, as described in subdivision (c) of Section 11110, before a product containing dextromethorphan may be purchased.

CHAPTER 4. PRESCRIPTIONS

Article 1 – Requirements of Prescriptions

11150. Persons Authorized to Write or Issue a Prescription

No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting

within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

11150.2 Cannabidiol – Impact of Federal Action on State Law

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

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

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

11150.3. Rescheduling of controlled substances

(a) Notwithstanding any other law, if a substance listed in Schedule I of Section 11054 is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of one of these substances is approved by the federal Food and Drug Administration and either placed on a schedule of the act other

than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within their scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.
(b) For purposes of this chapter, upon the effective date of any of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of the excluded substance may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.
(c) This section does not apply to cannabis or a cannabis product, as defined in Section 26001 of the Business and Professions Code. However, cannabis or cannabis products may be authorized pursuant to Section 11150.2.

11150.6. Methaqualone as Schedule I Controlled Substance

Notwithstanding Section 11150.5 or subdivision (a) of Section 11054, methaqualone, its salts, isomers, and salts of its isomers shall be deemed to be classified in Schedule I for the purposes of this chapter.

11151. Limitations on Filling Prescriptions From Medical Students

A prescription written by an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business and Professions Code, shall be filled only at a pharmacy maintained in the hospital which employs such unlicensed person.

11152. Nonconforming Prescriptions Prohibited

No person shall write, issue, fill, compound, or dispense a prescription that does not conform to this division.

11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

(b) Any person who knowingly violates this section shall be punished by imprisonment in the state prison or in the county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars ($20,000), or by both a fine and imprisonment.

(c) No provision of the amendments to this section enacted during the second year of the 1981-82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

11153.5. Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes.

(b) Anyone who violates this section knowing, or having a conscious disregard for the fact, that the controlled substances are for other than a legitimate medical purpose shall be punishable by imprisonment in the state prison, or in the county

jail not exceeding one year, or by a fine not exceeding twenty thousand dollars ($20,000), or by both a fine and imprisonment.

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, 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 the product.

11154. Prescription, etc. Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.

(a) Except in the regular practice of his or her profession, no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person or animal which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance, except as provided in this division.

(b) No person shall knowingly solicit, direct, induce, aid, or encourage a practitioner authorized to write a prescription to unlawfully prescribe, administer, dispense, or furnish a controlled substance.

11155. Prohibition on Physician Prescribing, etc. Where Controlled Substance Privileges Surrendered

Any physician, who by court order or order of any state or governmental agency, or who voluntarily surrenders his controlled substance privileges, shall not possess, administer, dispense, or prescribe a controlled substance unless and until such privileges have been restored, and he has obtained current registration from the appropriate federal agency as provided by law.

11156 Prescribing, etc., Controlled Substances to Addicts Only as Authorized

(a) Except as provided in Section 2241 of the Business and Professions Code, no person shall prescribe for, or administer, or dispense a controlled substance to, an addict, or to any person representing himself or herself as such, except as permitted by this division.

(b) (1) For purposes of this section, "addict" means a person whose actions are characterized by craving in combination with one or more of the following:

(A) Impaired control over drug use.

(B) Compulsive use.

(C) Continued use despite harm.

(2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section.

11157. No False or Fictitious Prescriptions

No person shall issue a prescription that is false or fictitious in any respect.

11158. Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration

(a) Except as provided in Section 11159 or in subdivision (b) of this section, no controlled substance classified in Schedule II shall be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance classified in Schedule III, IV, or V may be dispensed without a prescription meeting the requirements of this chapter.

(b) A practitioner specified in Section 11150 may dispense a controlled substance classified in Schedule II, which may be from a hospital pharmacy inventory, directly to an ultimate user in either of the following circumstances:

(1) In an amount not to exceed a 72-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only where the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours.

(2) For the purpose of initiating maintenance treatment or detoxification treatment, or both, for a person with an opioid use disorder. Not more than a three-day supply of such medication may be dispensed to the person at one time while arrangements are being made for referral for treatment. Such emergency treatment may not be renewed or extended.

(c) Except as otherwise prohibited or limited by law, a practitioner specified in Section 11150, may administer controlled substances in the regular practice of their profession.

11158.1. Prescribing Controlled Substance Containing an Opioid to a Minor

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

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

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

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

(4) Any other information required by law.

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

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

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

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

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

11159. Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years

An order for controlled substances for use by a patient in a county or licensed hospital shall be exempt from all requirements of this article, but shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually administered. The record of such orders shall be maintained as a hospital record for a minimum of seven years.

11159.1. Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years

An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This

section shall apply only to a clinic that has obtained a permit under the provisions of Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code. Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

11159.2. Exception to Controlled Substance Prescription Requirement; Terminally Ill Patient

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the

control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

11159.3 Filling Controlled Substance Prescription during Declared Emergency

(a) Notwithstanding any other law, during a declared local, state, or federal emergency, if the California State Board of Pharmacy issues a notice that the board is waiving the application of the provisions of, or regulations adopted pursuant to, the Pharmacy Law, as specified in subdivision (b) of Section 4062 of the Business and Professions Code, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription form meets the requirements of Section 11162.1, if the prescription meets the following requirements:

(1) Contains the information specified in subdivision (a) of Section 11164.

(2) Indicates that the patient is affected by a declared emergency with the words “11159.3 exemption” or a similar statement.

(3) Is written and dispensed within the first two weeks of the notice issued by the board. (b) A pharmacist filling a prescription pursuant to this section shall do all of the following:

(1) Exercise appropriate professional judgment, including reviewing the patient’s activity report from the CURES Prescription Drug Monitoring Program before dispensing the medication.

(2) If the prescription is for a Schedule II controlled substance, dispense no greater than the amount needed for a seven-day supply.

(3) Require the patient to first demonstrate, to the satisfaction of the pharmacist, their inability to access medications. This demonstration may include, but is not limited to, verification of residency within an evacuation area.

(c) A pharmacist shall not refill a prescription that has been dispensed pursuant to this section.

11161. Controlled Substance Prescription Blanks; Issuance by Department; Unlawful Possession; Restriction in Criminal Proceeding

(a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all controlled substance prescription forms in the practitioner's possession at a time set in the order and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription forms in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using controlled

substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

11161.5. Prescription Forms for Controlled Substance Prescriptions; Requirements

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

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

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

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

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

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

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

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

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

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign

level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (l) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall

be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

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

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

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

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

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

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

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

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

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

(n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the

denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):

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

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

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

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

11161.7. Prescriber Authority to Prescribe Restricted; Information to Board; Board Notification to Security Printers

(a) When a prescriber's authority to prescribe controlled substances is restricted by civil, criminal, or administrative action, or by an order of the court issued pursuant to Section 11161, the law enforcement agency or licensing board that sought the restrictions shall provide the name, category of licensure, license number, and the nature of the restrictions imposed on the prescriber to security printers, the Department of Justice, and the Board of Pharmacy.

(b) The Board of Pharmacy shall make available the information required by subdivision (a) to pharmacies and security printers to prevent the dispensing of controlled substance prescriptions issued by the prescriber and the ordering of additional controlled substance prescription forms by the restricted prescriber.

11162.1. Prescription Forms for Controlled Substances; Requirements

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

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

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

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

(4) A feature printed in thermochromic ink.

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

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

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

1–24

25–49

50–74

75–100

101–150

151 and over.

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

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

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

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

(11) The date of origin of the prescription.

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

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

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

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

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

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

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

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

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license

number, and federal controlled substance registration number of the prescriber on the form.

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

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

(d) Within the next working day following delivery, a security printer shall submit via Web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:

(1) Serial numbers of all prescription forms delivered.

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

(3) The delivery shipment recipient names.

(4) The date of delivery.

11162.5. Counterfeiting or Possession of Counterfeit Controlled Substance Prescription Blank; Penalty

(a) Every person who counterfeits a prescription blank purporting to be an official prescription blank prepared and issued pursuant to Section 11161.5, or knowingly possesses more than three counterfeited prescription blanks, shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of

the Penal Code or by imprisonment in a county jail for not more than one year.

(b) Every person who knowingly possesses three or fewer counterfeited prescription blanks purporting to be official prescription blanks prepared and issued pursuant to Section 11161.5, shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, or by a fine not exceeding one thousand dollars ($1,000), or by both that fine and imprisonment.

11162.6. Controlled Substance Prescription Form; Counterfeiting, Possession of, Attempt to Obtain or Obtain Under False Pretenses; Penalty

(a) Every person who counterfeits a controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail for not more than one year, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(b) Every person who knowingly possesses a counterfeited controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(c) Every person who attempts to obtain or obtains a controlled substance prescription form under false pretenses shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(d) Every person who fraudulently produces controlled substance prescription forms shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(e) This section shall become operative on July 1, 2004.

11164. Prescribing, Filling, Compounding or Dispensing Prescription for Controlled Substance; Requirements

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

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

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(e) This section shall become operative on January 1, 2005.

11164.1. Controlled Substance Prescription Issued in Another State for Delivery to Patient in Another State; Dispensing by California Pharmacy

(a) (1) Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) A prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) A pharmacy may dispense a prescription for a Schedule III, Schedule IV, or Schedule V controlled substance from an out-of-state prescriber pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2021.

11164.5. Electronic Prescriptions or Orders to Pharmacies and Hospitals

(a) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(b) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Department of Justice

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and

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

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

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

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the department, for educational, peer review, statistical, or research purposes, if patient information, including information that may identify the patient, is not compromised. The University of California shall be provided access to identifiable data for research purposes if the requirements of subdivision (t) of Section 1798.24 of the Civil Code are satisfied. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party, unless authorized by, or pursuant to, state and federal

privacy and security laws and regulations. The department shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

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

(C)(i) Notwithstanding subparagraph (A) or any other law, a state or local agency or employee, appointee, officer, contractor, or official or any other person acting on behalf of a public agency shall not knowingly provide any CURES data or knowingly expend or use time, money, facilities, property, equipment, personnel, or other resources in furtherance of any interstate investigation or proceeding seeking to impose civil, criminal, or disciplinary liability based on another state's laws for the provision or receipt of legally protected health care activity, as defined in Section 1798.300 of the Civil Code.

(ii) This section does not prohibit the investigation of any activity that is punishable as a crime under the laws of this state so long as CURES data related to any legally protected health care activity, as defined in Section 1798.300 of the Civil Code, is not knowingly shared with any individual or entity from another state.

(iii) This section does not prohibit compliance with an audit or investigation of activity that is unlawful under the laws of this state or federal law, or with an audit, review, or investigation conducted for purposes of licensure, registration, accreditation, or certification under the laws of this state or federal law or pursuant to an accrediting organization recognized by the State Department of Public Health or the federal Centers for Medicare and Medicaid Services.

(3) The department may adopt regulations regarding the access and use of the information within CURES. The department shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum,

address all of the following in a manner consistent with this chapter:

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

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

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

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

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

(d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:

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

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a prescriber using the federal

controlled substance registration number of a government-exempt facility.

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

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

(5) Quantity of the controlled substance dispensed.

(6) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, if available.

(7) Number of refills ordered.

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

(9) Prescribing date of the prescription.

(10) Date of dispensing of the prescription.

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

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

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

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

(h)(1) The department may enter into an agreement with an entity operating an interstate data sharing hub, or an agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information. An out-of-state authorized user who obtains CURES data through the interstate data sharing hub shall not provide any CURES data in furtherance of any investigation or proceeding seeking to impose civil, criminal, or disciplinary liability based on another state's laws for the provision or receipt of legally protected health care activity, as defined in Section 1798.300 of the Civil Code.

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

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

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

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

(6) Notwithstanding subdivision (c), the department shall not provide CURES data to out-of-state law enforcement absent a warrant, subpoena, or court order, issued pursuant to Section 2029.300 or 2029.350 of the Code of Civil Procedure, or Section 1326 of the Penal Code.

(i) Notwithstanding subdivision (d), a veterinarian shall report the information required by that subdivision to the department as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.

(j) If the dispensing pharmacy, clinic, or other dispenser experiences a temporary technological or electrical failure, it shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within its control. The deadline for transmitting prescription information to the department or contracted prescription data processing vendor pursuant to subdivision (d) shall be extended until the failure is corrected. If the dispensing pharmacy, clinic, or other dispenser experiences technological limitations that are not reasonably within its control, or is impacted by a natural or manmade disaster, the deadline for transmitting prescription information to the department or contracted prescription data processing vendor shall be extended until normal operations have resumed.

(k)(1) Any person who accesses the CURES database and who is not authorized by law to do so is guilty of a misdemeanor.

(2) Any person authorized by law to access the CURES database and who knowingly furnishes the information from the CURES database to a person who is not authorized by law to receive that information is guilty of a misdemeanor.

(3) This subdivision does not apply to a provider of health care as defined in Section 56.06 of the Civil Code that is subject to applicable state and federal medical privacy laws.

11165.1. History of Controlled Substances Dispensed to an Individual/PDMP

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III,

Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, upon receipt of a federal Drug Enforcement Administration (DEA) registration, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.

(iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.

(B) The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:

(i) Materially falsifying an application to access information contained in the CURES database. (ii) Failing to maintain effective controls for access to the patient activity report.

(iii) Having their federal DEA registration suspended or revoked.

(iv) Violating a law governing controlled substances or another law for which the possession or use of a controlled substance is an element of the crime.

(v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of a change to the subscriber account.

(D) An approved health care practitioner, pharmacist, or a 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) 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 certifies all of the following:

(i) The entity will not use or disclose data received from the CURES database for a 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, Schedule IV, or Schedule V 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) 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.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the 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 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 practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, or a 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 false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied

upon in the CURES database or for a 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, decision-making, 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.

(h) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

11165.2. CURES Violation: Citations; Request for Hearing; Fines

(a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its users.

(b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(c) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars ($2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be

deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not contested and a fine is not paid, the subscriber account will be terminated:

(A) A citation may be issued without the assessment of an administrative fine.

(B) Assessment of administrative fines may be limited to only particular violations of law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

11165.3. Report Theft/Loss of Security Forms

The theft or loss of prescription forms shall be reported immediately by the security printer or affected prescriber to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. This notification may be done in writing utilizing the approved Department of Justice form or may be reported by the authorized subscriber through the CURES Prescription Drug Monitoring Program.

11165.4. CURES; Prescribers' Duty Required to Consult

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

(iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical

record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.

(F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as

described in Section 4021.5 of the Business and Professions Code.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes buprenorphine or other controlled substance containing buprenorphine in the emergency department of a general acute care hospital.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.

(5) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.

(6) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.

(7) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.

(8) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(9) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health

care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) All applicable state and federal privacy laws govern the duties required by this section.

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

(g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

11165.5. CURES Funding; Definitions

(a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

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

(1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and

an admitted insurer writing workers' compensation insurance, as defined in Section 109 of the Insurance Code.

(4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

11165.6. Prescriber Access for List of Prescriber's Patients

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

11166. Time Limit for Filling a Controlled Substance Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited

No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

11167. Emergency Dispensing of Controlled Substance; Circumstances and Requirements

Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss

of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on January 1, 2005.

11167.5. Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements

(a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall,

prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) This section shall become operative on January 1, 2005.

11170. Prohibition on Prescribing, etc. Controlled Substance for Self

No person shall prescribe, administer, or furnish a controlled substance for himself.

11171. Prescribing, etc. Controlled Substance Only as Authorized

No person shall prescribe, administer, or furnish a controlled substance except under the conditions and in the manner provided by this division.

11172. Antedating or Postdating Prescription Prohibited

No person shall antedate or postdate a prescription.

11173. Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label

(a) No person shall obtain or attempt to obtain controlled substances, or procure or attempt to procure the administration of or prescription for controlled substances, (1) by fraud, deceit, misrepresentation , or subterfuge; or (2) by the concealment of a material fact.

(b) No person shall make a false statement in any prescription, order, report, or record, required by this division.

(c) No person shall, for the purpose of obtaining controlled substances, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, registered nurse, physician's assistant, or other authorized person.

(d) No person shall affix any false or forged label to a package or receptacle containing controlled substances.

11174. Prohibition on Providing False Name or Address in Connection with Prescription, etc.

No person shall, in connection with the prescribing, furnishing, administering, or dispensing of a controlled substance, give a false name or false address.

11175. Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription

No person shall obtain or possess a prescription that does not comply with this division, nor shall any person obtain a controlled substance by means of a prescription which does not comply with this division or possess a controlled substance obtained by such a prescription.

11179. Retention of Controlled Substance Prescription

A person who fills a prescription shall keep it on file for at least three years from the date of filling it.

11180. Prohibition of Controlled Substance Obtained or Possessed by Nonconforming Prescription

No person shall obtain or possess a controlled substance obtained by a prescription that does not comply with this division.

Article 2. Prescriber's Record

11190. Prescriber's Record for Schedule II. III or IV Controlled Substance; Prescription Requirements

(a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

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

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

(D) Quantity of the controlled substance dispensed.

(E) ICD-9 (diagnosis code), if available.

(F) Number of refills ordered.

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

(H) Date of origin of the prescription.

(2) (A) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly basis in a format set by the Department of Justice pursuant to regulation.

(B) The reporting requirement in this section shall not apply to the direct administration of a controlled substance to the body of an ultimate user or a prescription described in subdivision (k) of Section 11165. .

(d) This section shall become operative on January 1, 2005.

(e) The reporting requirement in this section for Schedule IV controlled substances shall not apply to any of the following:

(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.

(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the information required by this section for a Schedule II or Schedule III controlled substance, in a format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all of the following:

(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.

(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

11191. Retention Period; Violation

The record shall be preserved for three years. Every person who violates any provision of this section is guilty of a misdemeanor.

11192. Prima Facie Evidence of Violation of Section 11190

In a prosecution for a violation of Section 11190, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by a defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of a violation of the section.

Article 3. Copies of Prescriptions

11195. Providing Receipt for Prescription Removed by Peace Officer, Board Inspector, etc.

Whenever the pharmacist's copy of a controlled substance prescription is removed by a peace officer, agent of the Attorney General, or inspector of the Board of Pharmacy, or investigator of the Division of Investigation of the Department of Consumer Affairs for the purpose of investigation or as evidence, the officer or inspector or investigator shall give to the pharmacist a receipt in lieu thereof.

Article 4. Refilling Prescriptions

11200. Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Prohibited

(a) No person shall dispense or refill a controlled substance prescription more than six months after the date thereof.

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

(c) No prescription for a Schedule II substance may be refilled.

11201. Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements

A prescription for a controlled substance, except those appearing in schedule II, may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall refill only a reasonable amount sufficient to maintain the patient until the prescriber can be contacted. The pharmacist shall note on the reverse side of the prescription the date and quantity of the refill and that the prescriber was not available and the basis for his judgment to refill the prescription without the prescriber's authorization. The pharmacist shall inform the patient that the prescription was refilled without the prescriber's authorization, indicating that the prescriber was not available and that, in the pharmacist's professional judgment, failure to provide the drug might result in an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall inform the prescriber within a reasonable period of time. Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber.

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

Article 5. Pharmacists' Records

11205. Maintenance and Retention of Records in Separate File

The owner of a pharmacy or any person who purchases a controlled substance upon federal order forms as required pursuant to the provisions of the Federal "Comprehensive Drug Abuse Prevention and Control Act of 1970," (P.L. 91-513, 84 Stat. 1236), relating to the importation, exportation, manufacture, production, compounding, distribution, dispensing, and control of controlled substances, and who sells controlled substances obtained upon such federal order forms in response to

prescriptions shall maintain and file such prescriptions in a separate file apart from noncontrolled substances prescriptions. Such files shall be preserved for a period of three years.

11206. Required Information on Prescription

Filed prescriptions shall constitute a transaction record that, together with information that is readily retrievable in the pharmacy pursuant to Section 11164 shall show or include the following:

(a) The name(s) and address of the patient(s).

(b) The date.

(c) The character, including the name and strength, quantity, and directions for use of the controlled substance involved.

(d) The name, address, telephone number, category of professional licensure, and the federal controlled substance registration number of the prescriber.

11207. Only Pharmacist or Intern Authorized to Fill Prescription

(a) No person other than a pharmacist as defined in Section 4036 of the Business and Professions Code or an intern pharmacist, as defined in Section 4030 of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.

(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

11208. Prima Facie Evidence of Violation of Controlled Substance Act

In a prosecution under this division, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by the defendant is a lesser amount than is

accounted for by any record required by law is prima facie evidence of guilt.

11209. Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation

(a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

(b) The delivery receipt and any record of discrepancy shall be maintained by the wholesaler or manufacturer for a period of three years.

(c) A violation of this section is a misdemeanor.

(d) Nothing in this section shall require a common carrier to label a package containing controlled substances in a manner contrary to federal law or regulation.

CHAPTER 5. USE OF CONTROLLED SUBSTANCES

Article 1. Lawful Medical Use Other Than Treatment of Addicts

11210. Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed

A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and

Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

The physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment.

The physician, surgeon, dentist, veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business

and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

11211. Purchases of Controlled Substances by Hospital Without a Pharmacist for Emergencies; Conditions on Providing to Patients

In order to provide a supply of controlled substances as may be necessary to handle emergency cases, any hospital which does not employ a resident pharmacist and which is under the supervision of a licensed physician, may purchase controlled substances on federal order forms for such institution, under the name of such hospital, such supply to be made available to a registered nurse for administration to patients in emergency cases, upon direction of a licensed physician.

11212. Obtaining and Using Controlled Substance for Research, Instruction, or Analysis; Conditions

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes those substances classified in paragraphs (45) and (46) of subdivision (b) of Section 11054 of the Health and Safety Code, upon registration with and approval by the California Department of Justice for use of those substances in bona fide research, instruction, or analysis.

That research, instruction, or analysis shall be carried on only under the auspices of the individual identified by the registrant as responsible for the research. Complete records of receipts,

stocks at hand, and use of these controlled substances shall be kept.

The Department of Justice may withdraw approval of the use of such substances at any time. The department may obtain and inspect at any time the records required to be maintained by this section.

11213. Research Approval by Research Advisory Panel

(a) Persons who, under applicable federal laws or regulations, are lawfully entitled to use Schedule I, Schedule II, or both, controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use those substances, as defined in this division, for those purposes upon approval for use of those controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480.

(b) Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project that has been approved by the Research Advisory Panel pursuant to Section 11480.1. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Article 2. Treatment of Addicts for Addiction

11215. Administration of Narcotics By or Under Direction of Physician, etc.; Who Physician May Direct to Administer

(a) Except as provided in subdivision (b), any narcotic controlled substance employed in treating an addict for addiction shall be administered by:

(1) A physician and surgeon.

(2) A registered nurse acting under the instruction of a physician and surgeon.

(3) A physician assistant licensed pursuant to Chapter 7.7 (commencing with Section 3500) of Division 2 of the Business and Professions Code acting under the patient-specific authority of his or her physician and surgeon supervisor approved pursuant to Section 3515 of the Business and Professions Code.

(b) When acting under the direction of a physician and surgeon, the following persons may administer a narcotic controlled substance orally in the treatment of an addict for addiction to a controlled substance:

(1) A psychiatric technician licensed pursuant to Chapter 10 (commencing with Section 4500) of Division 2 of the Business and Professions Code.

(2) A vocational nurse licensed pursuant to Chapter 6.5 (commencing with Section 2840) of Division 2 of the Business and Professions Code.

(3) A pharmacist licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.

(c) Except as permitted in this section, no person shall order, permit, or direct any other person to administer a narcotic controlled substance to a person being treated for addiction to a controlled substance.

11217. Authorized Place of Treatment

Except as provided in Section 11223, no person shall treat an addict for addiction to a narcotic drug except in one of the following:

(a) An institution approved by the State Department of Health Care Services, and where the patient is at all times kept under restraint and control.

(b) A city or county jail.

(c) A state prison.

(d) A facility designated by a county and approved by the State Department of Health Care Services pursuant to Division 5 (commencing with Section 5000) of the Welfare and Institutions Code.

(e) A state hospital.

(f) A county hospital.

(g) A facility licensed by the State Department of Health Care Services pursuant to Division 10.5 (commencing with Section 11750).

(h) A facility as defined in subdivision (a) or (b) of Section 1250 and Section 1250.3.

A narcotic controlled substance in the continuing treatment of addiction to a controlled substance shall be used only in those programs licensed by the State Department of Health Care Services pursuant to Article 1 (commencing with Section 11839) of Chapter 10 of Part 2 of Division 10.5 on either an inpatient or outpatient basis, or both.

This section does not apply during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age.

Neither this section nor any other provision of this division shall be construed to prohibit the maintenance of a place in which persons seeking to recover from addiction to a controlled substance reside and endeavor to aid one another and receive aid from others in recovering from that addiction, nor does this section or this division prohibit that aid, provided that no person is treated for addiction in a place by means of administering, furnishing, or prescribing of controlled substances. The preceding sentence is declaratory of preexisting law.

Neither this section or any other provision of this division shall be construed to prohibit short-term narcotic detoxification treatment in a controlled setting approved by the director and pursuant to rules and regulations of the director. Facilities and treatment approved by the director under this paragraph shall not be subject to approval or inspection by the Medical Board of California, nor shall persons in those facilities be required to register with, or report the termination of residence with, the police department or sheriff's office.

11217.5. Administration in Office or Medical Facility of Non-Narcotic Drugs

Notwithstanding the provisions of Section 11217, a licensed physician and surgeon may treat an addict for addiction in any office or medical facility which, in the professional judgment of such physician and surgeon, is medically proper for the

rehabilitation and treatment of such addict. Such licensed physician and surgeon may administer to an addict, under his direct care, those medications and therapeutic agents which, in the judgment of such physician and surgeon, are medically necessary, provided that nothing in this section shall authorize the administration of any narcotic drug.

11218. Limitation on Narcotics in First 15 Days of Treatment

A physician treating an addict for addiction may not prescribe for or furnish to the addict more than any one of the following amounts of controlled substances during each of the first 15 days of that treatment:

(a) Eight grains of opium.
(b) Four grains of morphine.
(c) Six grains of Pantopon.
(d) One grain of Dilaudid.
(e) Four hundred milligrams of isonipecaine (Demerol).

11219. Limitation on Narcotics after First 15 Days of Treatment

After 15 days of treatment, the physician may not prescribe for or furnish to the addict more than any one of the following amounts of controlled substances during each day of the treatment:

(a) Four grains of opium.
(b) Two grains of morphine.
(c) Three grains of Pantopon.
(d) One-half grain of Dilaudid.
(e) Two hundred milligrams of isonipecaine (Demerol).

11220. Required Discontinuance of Controlled Substances, Except Methadone or LAAM, After 30 Days

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

11222. Persons in Custody: Treatment for Withdrawal Symptoms; Continued Participation in Narcotic Treatment Programs

In any case in which a person is taken into custody by arrest or other process of law and is lodged in a jail or other place of confinement, and there is reasonable cause to believe that the person is addicted to a controlled substance, it is the duty of the person in charge of the place of confinement to provide the person so confined with medical aid as necessary to ease any symptoms of withdrawal from the use of controlled substances.

In any case in which a person, who is participating in a narcotic treatment program, is incarcerated in a jail or other place of confinement, he or she shall, in the discretion of the director of the program, be entitled to continue in the program until conviction.

Article 3. Veterinarians

11240. Prohibition on Prescribing, etc. Controlled Substance for Human Being

No veterinarian shall prescribe, administer, or furnish a controlled substance for himself or any other human being.

11241. Prescription Contents

A prescription written by a veterinarian shall state the kind of animal for which ordered and the name and address of the owner or person having custody of the animal.

Article 4. Sale Without Prescription

11250. Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form

(a) No prescription is required in case of the sale of controlled substances at retail in pharmacies by pharmacists to any of the following:

(1) Physicians.

(2) Dentists.

(3) Podiatrists.

(4) Veterinarians.

(5) Pharmacists acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurses acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistants acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107.

(6) Optometrist.

(b) In any sale mentioned in this article, there shall be executed any written order that may otherwise be required by federal law relating to the production, importation, exportation, manufacture, compounding, distributing, dispensing, or control of controlled substances.

11251. Authorized Wholesale by Pharmacists

No prescription is required in case of sales at wholesale by pharmacies, jobbers, wholesalers, and manufacturers to any of the following:

(a) Pharmacies as defined in the Business and Professions Code.

(b) Physicians.

(c) Dentists.

(d) Podiatrists.

(e) Veterinarians.

(f) Other jobbers, wholesalers or manufacturers.

(g) Pharmacists acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurses acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistants acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107.

(h) Optometrists.

11252. Preservation of Federally Required Form

All wholesale jobbers, wholesalers, and manufacturers, mentioned in this division shall keep, in a manner readily accessible, the written orders or blank forms required to be preserved pursuant to federal law relating to the production, importation, exportation, manufacture, compounding, distributing, dispensing, or control of controlled substances.

11253. Duration of Retention

The written orders or blank forms shall be preserved for at least three years after the date of the last entry made.

11255. Actions Constituting Sale

The taking of any order, or making of any contract or agreement, by any traveling representative or employee of any person for future delivery in this state, of any controlled substance constitutes a sale within the meaning of this division.

11256. Required Report of Order by or Sale to Out-of-State Wholesaler or Manufacturer

Within 24 hours after any purchaser in this state gives any order for a controlled substance classified in Schedule II to, or makes any contract or agreement for purchases from or sales by, an out-of-state wholesaler or manufacturer of any controlled substances for delivery in this state, the purchaser shall forward to the Attorney General by registered mail a true and correct copy of the order, contract, or agreement.

11364. Possession of Illegal Drug Paraphernalia

(a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e) or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance that is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of hypodermic needles or syringes.

DIVISION 105. COMMUNICABLE DISEASE PREVENTION AND CONTROL

CHAPTER 13. ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) IMMUNIZATION

121281. Board Web Site: Testing for HIV and Viral Hepatitis; Disposal of Sharps Waste; How to Access Drug Treatment

In order to assist pharmacists and pharmacy personnel in the education of consumers who are at risk of bloodborne infections regarding methods and opportunities for improving and protecting their health, and thereby protect the public health, the Office of AIDS shall develop and maintain all of the following information, on its Internet Web site, and the California State

Board of Pharmacy shall also post, or maintain a link to, the information on its Internet Web site:

(a) How consumers can access testing and treatment for HIV and viral hepatitis.

(b) How consumers can safely dispose of syringes and hypodermic needles or other sharps waste.

(c) How consumers can access drug treatment.

CHAPTER 18. CLEAN NEEDLE AND SYRINGE EXCHANGE PROGRAM

121349. **Legislative Findings and Declaration**

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

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

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under

this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Authorization shall be made after consultation with the local health officer and local law enforcement leadership, and after a period of public comment, as described in subdivision (e). In making the determination, the department shall balance the concerns of law enforcement with the public health benefits. The authorization shall not be for more than two years. Before the end of the two-year period, the department may reauthorize the program in consultation with the local health officer and local law enforcement leadership.

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

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

(A) Drug abuse treatment services.

(B) HIV or hepatitis screening.

(C) Hepatitis A and hepatitis B vaccination.

(D) Screening for sexually transmitted infections.

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

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

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

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

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

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

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

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

(A) The total number of persons served.

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

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

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

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

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

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

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

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

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

approval shall not be subject to the noticing requirements of subdivision (e).

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

121349.1. Needle and Syringe Exchange Project; Requirements

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

121349.2. Local, Health and Law Enforcement Comment Biennially, Public Input

Local government, local health officials, and law enforcement shall be given the opportunity to comment on clean needle and

syringe exchange programs on a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

121349.3. **Biennial Report of Health Officer of Participating Jurisdiction**

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

DIVISION 106. PERSONAL HEALTH CARE

PART 4.5. PAIN PATIENT'S BILL OF RIGHTS

124960. Treatment of Severe Chronic Intractable Pain

The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the

patient that there are physicians who treat severe chronic intractable pain with methods that include the use of opiates.

124961. Pain Patient's Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient who suffers from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve that pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who treat pain and whose methods include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain, as long as that prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the

Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

DIVISION 106. PERSONAL HEALTH CARE
PART 5. HEREDITARY DISEASES/CONGENITAL DEFECTS
CHAPTER 2. GENETIC DISEASE SERVICES

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.10. Article Title

This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.15. Legislative Declarations

The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors has provided people with hemophilia and other bleeding disorders the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations according to the federal Centers for Disease Control and Prevention and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.

(h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.20. Definitions

Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

(a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting

product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(c) “Bleeding disorder” means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called “factors,” including all forms of hemophilia and other bleeding disorders that, without treatment, result in uncontrollable bleeding or abnormal blood clotting.

(d) “Blood clotting product” means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, factor VII, factor VIIa, factor VIII, and factor IX products, von Willebrand factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) “Emergency” means care as defined in Section 1317.1.

(f) “Hemophilia” means a human bleeding disorder caused by a hereditary deficiency of the factor I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) “Hemophilia treatment center” means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

(h) “Home use” means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

(i) “Patient” means a person needing a blood clotting product for home use.

(j) (1) “Provider of blood clotting products for home use” means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

(2) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.25. Requirements for Providers of Blood Clotting Products for Home Use

Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors.

(c) Maintain 24-hour on-call service seven days a week for every day of the year, adequately screen telephone calls for emergencies, acknowledge all telephone calls within one hour or less, and have access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.

(d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained.

(e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(g) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(h) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(i) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(j) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(k) Provide language interpretive services over the telephone or in person, as needed by the patient.

(l) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(m) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(n) Comply with the privacy and confidentiality requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.30. Administration and Enforcement

The California State Board of Pharmacy shall administer and enforce this article.

125286.35. Exemptions

Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood clotting products for home use.

DIVISION 114. Prescription Drug Discount Prohibition

132000. Prescription Drug Discount Prohibition – Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations"

(a) Except as provided in Section 132004, a person who manufactures a prescription drug shall not offer in the state a discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses associated with his or her health insurance, health care service plan, or other health coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if a lower cost generic drug is covered under the individual's health insurance, health care service plan, or other health coverage on a lower cost-sharing tier that is designated to be therapeutically

equivalent as indicated by the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations."

(b) The prohibition in subdivision (a) shall not apply to a branded prescription drug, until the time that the first drug designated in the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" as therapeutically equivalent to that branded prescription drug has been nationally available for three calendar months.

132002. Prescription Drug Discount Prohibition – Active Ingredients Regulated by Food and Drug Administration, Available at Lower Cost and Otherwise Not Contraindicated

Except as provided in Section 132004, a person who manufactures a prescription drug shall not offer in the state a discount, repayment, product voucher, or other reduction in the individual's out-of-pocket expenses associated with his or her health insurance, health care service plan, or other health coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if the active ingredients of the drug are contained in products regulated by the federal Food and Drug Administration, are available without prescription at a lower cost, and are not otherwise contraindicated for treatment of the condition for which the prescription drug is approved.

132004. Prescription Drug Discount Prohibition – Exceptions

The prohibitions in Sections 132000 and 132002 shall not apply to any of the following:

(a) A discount, repayment, product voucher, or other payment to a patient or another person on the patient's behalf for a prescription drug required under a United States Food and Drug Administration Risk Evaluation and Mitigation Strategy for the purpose of monitoring or facilitating the use of that prescription drug in a manner consistent with the approved labeling of the prescription drug.

(b) A single-tablet drug regimen for treatment or prevention of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) that is as effective as a multitablet regimen, unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally effective or more effective and is more likely to result in adherence to the drug regimen.

(c) The individual has completed any applicable step therapy or prior authorization requirements for the branded prescription drug as mandated by the individual's health insurer, health care service plan, or other health coverage.

(d) A discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses is not associated with his or her health insurance, health care service plan, or other health coverage.

(e) Rebates received by a state agency.

132006. Prescription Drug Discount Prohibition – Exception if Product is Free for Patient and Insurer, Health Care Service Plan or Other Health Coverage

This division does not prohibit an entity, including an entity that manufactures prescription drugs or a patient assistance program that is solely funded by one or more manufacturers, from offering a pharmaceutical product free of any cost, if the product is free of cost to both the patient and his or her health insurer, health care service plan, or other health coverage.

132008. Pharmacist's Ability to Substitute Prescription Drug; Assistance by Independent Charity Patient Assistance Program; Assistance by Pharmaceutical Manufacturer

(a) This division shall not be deemed to affect a pharmacist's ability to substitute a prescription drug pursuant to Section 4073 of the Business and Professions Code.

(b) (1) This division shall not prohibit or limit assistance to a patient provided by an independent charity patient assistance program.

(2) For purposes of this section, "independent charity patient assistance program" means a program that meets all of the following requirements:

(A) The program does not allow a pharmaceutical manufacturer or an affiliate of the manufacturer, including, but not limited to, an employee, agent, officer, shareholder, contractor, wholesaler, distributor, or pharmacy benefits manager, to exert any direct or indirect influence or control over the charity or subsidy program.

(B) Assistance is awarded in a truly independent manner that severs any link between a pharmaceutical manufacturer's funding and the beneficiary.

(C) Assistance is awarded without regard to the pharmaceutical manufacturer's interest and without regard to the beneficiary's choice of product, provider, practitioner, supplier, health insurance, health care service plan, or other health coverage.

(D) Assistance is awarded based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

(E) The pharmaceutical manufacturer does not solicit or receive data from the program that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

DIVISION 116. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION

CHAPTER 2. HEALTH FACILITIES

150200. Legislative Intent to Establish Voluntary Drug Repository and Distribution Program

It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. It is also the intent of the Legislature that the health and safety of Californians are

protected and promoted through this program, while reducing unnecessary waste at licensed health and care facilities, by allowing those facilities to donate unused and unexpired medications that were never in the hands of a patient or resident and for which no credit or refund to the patient or resident could be received.

150201. Definitions

(a) "Donor organization" means an entity described in subdivision (a) of Section 150202.

(b) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.

(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

(c) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(d) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

150202. Authorized Donations of Unused Medications

(a) Notwithstanding any other law, a donor organization is defined, for purposes of this division, to refer to the following

facilities, hospitals, and entities that legally possess centrally stored, unused medication:

(1) A licensed general acute care hospital, as defined in Section 1250.

(2) A licensed acute psychiatric hospital, as defined in Section 1250.

(3) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.

(4) A licensed intermediate care facility, as defined in Section 1250.

(5) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.

(6) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.

(7) A licensed correctional treatment center, as defined in Section 1250.

(8) A licensed psychiatric health facility, as defined in Section 1250.2.

(9) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.

(10) A licensed residential care facility for the elderly, as defined in Section 1569.2, with 16 or more residents.

(11) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

(12) An eligible entity, as defined in subdivision (b) of Section 150201.

(13) A juvenile facility, as described in Section 208.3 of the Welfare and Institutions Code.

(14) A local detention facility, as described in Section 6031.4 of the Penal Code.

(15) A facility that is any of the following:

(A) Licensed by the State Department of Social Services.

(B) Licensed by the State Department of Public Health.

(C) Licensed by the State Department of Health Care Services.

(D) Licensed by or under the jurisdiction of the Department of Corrections and Rehabilitation.

(E) Licensed by or under the jurisdiction of the Division of Juvenile Justice.

(16) A licensed home health agency, as defined in Section 1725.

(17) A licensed hospice agency, as defined in Section 1745.

(18) A licensed hospice facility, as defined in subdivision (n) of Section 1250.

(b) Medication donated by health and care facilities pursuant to subdivision (a) shall meet the requirements of subdivisions (c) and (d) of Section 150204 and shall be unexpired medication that would have otherwise been destroyed by the facility or another appropriate entity.

(c) Medication eligible for donation by facilities pursuant to subdivision (a) shall be directly delivered from the dispensing pharmacy, wholesaler or manufacturer, to the facility and subsequently centrally stored. Centrally stored medication that originated from a patient or resident is not eligible for donation under this division.

150202.5. Authorized Donations of Unused Medications; Manufacturer Medications

Notwithstanding any other law, a pharmacy, licensed in California and not on probation with the California State Board of Pharmacy may donate unused, unexpired medication that meets the requirements of subdivisions (c) and (d) of Section 150204, under a program established pursuant to this division and that meets either of the following requirements:

(a) The medication was received directly from a manufacturer or wholesaler.

(b) The medication was returned from a health facility to the issuing pharmacy, in a manner consistent with state and federal law.

150203. Drug Wholesalers or Manufacturers May Donate Unused Medications

Notwithstanding any other provision of law, a wholesaler licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code

and a drug manufacturer that is legally authorized under federal law to manufacture and sell pharmaceutical drugs may donate unused medications under the voluntary drug repository and distribution program established by a county pursuant to this division.

150204. County May Establish Repository and Distribution Program for Dispensing Donated Drugs

(a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in Section 150201, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set

by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor.

Donated medication that does not meet the requirements of this division shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) (1) Except as provided in paragraph (2), medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(2) A pharmacy that exists solely to operate the repository and distribution program may repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in

Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

150204.5. Repository and Distribution Pilot Program

(a)(1) A regional pilot program may be established in the Counties of Santa Clara and San Mateo and the City and County of San Francisco to determine the feasibility and benefits of implementing and maintaining a repository and distribution program. The regional pilot program shall run until January 1, 2030.

(b) Participating pharmacies in the regional pilot program shall be owned or operated by the Counties of Santa Clara or San Mateo or the City and County of San Francisco, licensed in California, and not on probation with the California State Board of Pharmacy.

(c)(1) Participants in the regional pilot program shall develop and implement their programs in accordance with this division.

(2) While participating in the regional pilot program, participants shall continue to meet all other legal responsibilities and requirements relating to pharmacy services and comply with all relevant state and federal statutes when administering their programs.

(d) Section 150204 shall not apply to a pilot program established pursuant to this section and Section 150204.6

150204.6. Repository and Distribution Pilot Program Requirements

(a)(1) A county specified in Section 150204.5 may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4)(A) A participating primary care clinic, as described in Section 150201, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(B) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall

provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall each ensure that this notice is also provided to the other two entities.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Medication donated to the repository and distribution program or transferred between participating entities shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a hospital, facility, or entity, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d)(1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2)(A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use their professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this

division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division may be transferred more than once only within the county and after the final transfer shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, original manufacturer lot numbers, and current expiration date. The document shall include a statement that the medication shall be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(D) Medication donated from multiple facilities under this division may be commingled by the participating entity. However, in the event of a recall, recalled medication shall be destroyed at the National Drug Code level.

(E) Participating facilities shall maintain a system for recording and logging donated medication which allows the tracking of medication in each repackaged container back to the facility or facilities that donated the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. Donated medication that does not meet the requirements of this division shall not be sold, dispensed, or otherwise transferred to any other entity.

(i)(1) When dispensed to an eligible patient under this program, the donated medication shall be in a new, properly labeled

container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. However, medications donated in sealed manufacturer's packaging are not required to be placed into a new container, but shall otherwise be appropriately labeled. Expired medication shall not be dispensed.

(2) The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date. Repackaged medication can only be dispensed to patients within the county.

(j) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. Notwithstanding any other law, the acquisition record created by a participating entity may be used as the donation, destruction, or disposition record required of a donor organization for donated medication.

(k) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(l) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, a biological product as defined in Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(m) Notwithstanding any other law, a participating entity shall follow the same federal and state procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

(n) On January 1, 2028, the Board of Pharmacy shall submit to the Legislature an evaluation of the regional pilot programs and

pilot participants' compliance to program requirements as specified in this division. The report shall comply with Section 9795 of the Government Code.

(o) A participating entity shall disclose to the Board of Pharmacy any "medication errors," as that term is described in Section 1716 of Title 16 of the California Code of Regulations, arising out of a program under this division, within 30 days of a participating entity discovering the medication error.

(p) This section shall remain in effect only until January 1, 2030, and as of that date is repealed.

150205. Liability

(a) The following persons and entities shall not be subject to criminal or civil liability for injury caused when any entity or person donates, accepts, or dispenses prescription drugs in compliance with this division:

(1) A prescription drug manufacturer, wholesaler, governmental entity, or participating entity.

(2) A pharmacist or physician who accepts or dispenses prescription drugs.

(3) A licensed facility, as described in Section 150202, or a pharmacy, as described in Section 150202.5.

(b) A surplus medication collection and distribution intermediary, as described in Section 150208, shall not be subject to criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with this division.

150206. No Immunity for Noncompliance or Negligence

The immunities provided in Section 150205 shall not apply in cases of noncompliance with this division, bad faith, or gross negligence.

150207. Disciplinary Actions

Nothing in this division shall affect disciplinary actions taken by licensing and regulatory agencies.

150208. Surplus Medication Collection and Distribution Intermediary; Requirements

(a) A surplus medication collection and distribution intermediary that is licensed pursuant to Section 4169.5 of the Business and Professions Code, established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a program established pursuant to this division is authorized to operate under this section.

(b) A surplus medication collection and distribution intermediary shall comply with the following:

(1) It shall not take possession, custody, or control of dangerous drugs and devices.

(2) It shall ensure that notification is provided to participating entities that a package has been shipped when the surplus medication collection and distribution intermediary has knowledge of the shipment and provided logistical support to facilitate a shipment directly from a donor organization, as defined in subdivision (a) of Section 150202, to a participating entity.

(3) It shall not select, or direct a donor organization, as defined in subdivision (a) of Section 150202, to select, a specific participating entity to receive surplus medications.

(c) A surplus medication collection and distribution intermediary is authorized to do the following:

(1) Charge membership, administrative, or overhead fees sufficient to cover the reasonable costs of the support and services provided.

(2) Contract directly with a county to facilitate the donation of medications to or transfer of medications between participating entities and provide general support in a county's implementation of a program established pursuant to this division.

(d) No participating entities shall receive donated medication directly from the surplus medication collection and distribution intermediary.

DIVISION 117. CANCER MEDICATION RECYCLING ACT

150400. Name of Act

This division shall be known, and may be cited, as the Cancer Medication Recycling Act.

150401. Definitions

For purposes of this division, the following definitions apply:

(a) “Donor” means an individual who donates unused prescription drugs to a participating practitioner for the purpose of redistribution to established patients of that practitioner.

(b) “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program established pursuant to this division. “Ineligible drugs” include all controlled substances, including all opioids, all compounded medications, injectable medications, drugs that have an approved United States Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.

(c) “Participating practitioner” means a person who is licensed to practice medicine by the Medical Board of California and is board certified in medical oncology or hematology and is registered with a surplus medication collection and distribution intermediary.

(d) “Recipient” means an individual who voluntarily receives donated prescription medications.

(e) “Surplus medication collection and distribution intermediary” means an entity licensed pursuant to Section 4169.5 of the Business and Professions Code as a surplus medication collection and distribution intermediary, as described in Section 150208.

(f) “Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” as defined in Section 4022 of the Business and Professions Code or a “drug” as defined in Section 4025 of the Business and Professions Code, that is prescribed as part of a cancer treatment plan and is in its original container or packaging.

150402. An unused cancer medication that is not an ineligible drug as defined in subdivision (b) of Section 150401 may be

donated to a participating practitioner, and a participating practitioner may accept and redistribute the donated prescription drugs.

150403. Requirements for Participating Practitioner

(a) A participating practitioner shall comply with all of the following:

(1) Be registered with a surplus medication collection and distribution intermediary in order to participate in the program established pursuant to this division and Article 11.7 (commencing with Section 4169.7) of Chapter 9 of Division 2 of the Business and Professions Code.

(2) Only accept donated medications originally prescribed for use by established patients of that participating practitioner or practice.

(3) Distribute a medication only if it will not expire before the proper use by the recipient based on the participating practitioner's directions for use.

(4) Refuse a medication that has previously been redistributed.

(5) Store all donated medications separately from all other medication stock.

(6) Store all donated medications in compliance with the manufacturer's storage requirements per the drug monograph.

(7) Remove or redact all confidential patient information, personal information, and any other information through which the prior patient could be identified from donated medications.

(8) Require all donors to read and sign the donor form approved by the surplus medication collection and distribution intermediary.

(9) Keep all donor forms and recipient forms in the records for at least three years.

(10) Examine the donated drug to determine that it has not been adulterated or misbranded and certify that the medication has been stored in compliance with the requirements of the product.

(11) Require all recipients of a donated medication to read and sign the recipient form approved by the surplus medication collection and distribution intermediary.

(12) Dispose of any donated medications that were collected but not redistributed in accordance with all local, state, and federal requirements for the disposal of medications.

(13) Monitor all United States Food and Drug Administration (FDA) or manufacturer recalls, market withdrawals, and safety alerts and communicate with recipients if medications they received may be impacted by the FDA action.

(14) Inspect all donated medications to determine that the drugs are unaltered, safe, and suitable for redistribution and meet all of the following conditions:

(A) Tamper-resistant packaging is unopened and intact or, in the case of unit dose packaging, the tamper-resistant dose packaging is intact for each dose donated.

(B) Tablets or capsules have a uniformity of color, shape, imprint or markings, texture, and odor.

(C) Liquids have a uniformity of color, thickness, particulates, transparency, and odor.

(D) The date of donation is less than six months from the date of the initial prescription or prescription refill.

(15) Establish policies and procedures for the administration of the cancer medication recycling program, including, but not limited to, criteria for determining medication distribution to patients. Provide the surplus medication collection and distribution intermediary with updated sections of their policy and procedures manual that indicate how the practitioner will accept, reuse, and keep records of donated medications, if requested.

(b) A donor is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, as set forth in Part 5 (commencing with Section 109875) of Division 104, for an injury caused when donating, accepting, or dispensing medication in compliance with this division, unless an injury arising from the donated medication is caused by the gross negligence,

recklessness, or intentional conduct of the donor, or in cases of noncompliance with this division.
(c) A participating practitioner that receives and redistributes a donated medication is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, as set forth in Part 5 (commencing with Section 109875) of Division 104, resulting from the condition of the donated medication unless an injury arising from the donated medication is caused by the gross negligence, recklessness, or intentional conduct of the participating practitioner, in cases of noncompliance with this division, or in cases of malpractice unrelated to the quality of the medication.
(d) The following persons and entities are not subject to criminal or civil liability for an injury caused when participating in the program established pursuant to this division, including, but not limited to, donating, accepting, or dispensing prescription drugs in compliance with this division:
(1) A prescription drug manufacturer, wholesaler, or participating entity.
(2) A participating practitioner who accepts or dispenses prescription drugs.
(3) A donor, as defined in Section 150401.
(4) A surplus medication collection and distribution intermediary.
(e) The immunities provided in subdivision (d) do not apply in cases of noncompliance with this division, gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the medication.
(f) This division shall not affect disciplinary actions taken by licensing and regulatory agencies.

150404. Division Repeal Date
This division shall remain in effect only until January 1, 2027, and as of that date is repealed.

CALIFORNIA CIVIL CODE

Division 1. Persons

PART 2.6. CONFIDENTIALITY OF MEDICAL INFORMATION

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CONFIDENTIALITY OF MEDICAL INFORMATION

56. Citation/Confidentiality of Medical Information Act

This part may be cited as the Confidentiality of Medical Information Act.

56.05. Definitions

For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) “Authorized recipient” means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.

(c) “Confidential communications request” means a request by a subscriber or enrollee that health care service plan communications containing medical information be communicated to him or her at a specific mail or email address or specific telephone number, as designated by the subscriber or enrollee.

(d) “Contractor” means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. “Contractor” does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) “Enrollee” has the same meaning as that term is defined in Section 1345 of the Health and Safety Code.

(f) “Expiration date or event” means a specified date or an occurrence relating to the individual to whom the medical information pertains or the purpose of the use or disclosure, after which the provider of health care, health care service plan, pharmaceutical company, or contractor is no longer authorized to disclose the medical information.

(g) “Health care service plan” means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(h) “Licensed health care professional” means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(i) “Marketing” means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. “Marketing” does not include any of the following:

(1) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(2) Communications made to current enrollees solely for the purpose of describing a provider’s participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(3) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual’s adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(A) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(B) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(C) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(j)(1) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental health application information, reproductive or sexual health application information, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(2) If individually identifying information regarding immigration status, including current and prior immigration status, or place of birth, is known or collected in electronic or physical form by a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, it shall be treated as medical information, as defined in paragraph (1).

(k) "Mental health application information" means information related to a consumer's inferred or diagnosed mental health or substance use disorder, as defined in Section 1374.72 of the Health and Safety Code, collected by a mental health digital service.

(l) “Mental health digital service” means a mobile-based application or internet website that collects mental health application information from a consumer, markets itself as facilitating mental health services to a consumer, and uses the information to facilitate mental health services to a consumer.

(m) “Patient” means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(n) “Pharmaceutical company” means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. “Pharmaceutical company” does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(o) “Protected individual” means any adult covered by the subscriber’s health care service plan or a minor who can consent to a health care service without the consent of a parent or legal guardian, pursuant to state or federal law. “Protected individual” does not include an individual that lacks the capacity to give informed consent for health care pursuant to Section 813 of the Probate Code.

(p) “Provider of health care” means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. “Provider of health care” does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

(q) “Reproductive or sexual health application information” means information about a consumer’s reproductive health, menstrual cycle, fertility, pregnancy, pregnancy outcome, plans to conceive, or type of sexual activity collected by a reproductive or sexual health digital service, including, but not limited to,

information from which one can infer someone's pregnancy status, menstrual cycle, fertility, hormone levels, birth control use, sexual activity, or gender identity.

(r) "Reproductive or sexual health digital service" means a mobile-based application or internet website that collects reproductive or sexual health application information from a consumer, markets itself as facilitating reproductive or sexual health services to a consumer, and uses the information to facilitate reproductive or sexual health services to a consumer.

(s) "Sensitive services" means all health care services described in Sections 6924, 6925, 6926, 6927, 6928, and 6929 of the Family Code, and Sections 121020 and 124260 of the Health and Safety Code, obtained by a patient at or above the minimum age specified for consenting to the service specified in the section.

(t) "Subscriber" has the same meaning as that term is defined in Section 1345 of the Health and Safety Code.

(u) "Immigration enforcement" means any and all efforts to investigate, enforce, or assist in the investigation or enforcement of any federal civil immigration law, and also includes any and all efforts to investigate, enforce, or assist in the investigation or enforcement of any federal criminal immigration law that penalizes a person's presence in, entry or reentry to, or employment in, the United States.

56.06. Application to Businesses

(a) Any business organized for the purpose of maintaining medical information, as defined in subdivision (g) of Section 56.05, in order to make the information available to an individual or to a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage the individual's information, or for the diagnosis and treatment of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, nothing in this section shall be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(b) Any business that offers software or hardware to consumers, including a mobile application or other related device that is designed to maintain medical information, as defined in subdivision (j) of Section 56.05, in order to make the information available to an individual or a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage the individual's information, or for the diagnosis, treatment, or management of a medical condition of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, nothing in this section shall be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

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

(d) Any business that offers a mental health digital service to a consumer for the purpose of allowing the individual to manage the individual's information, or for the diagnosis, treatment, or management of a medical condition of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(e) Any business that offers a reproductive or sexual health digital service to a consumer for the purpose of allowing the individual to manage the individual's information, or for the diagnosis, treatment, or management of a medical condition of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including, but not limited to, laws that specifically incorporate by reference the definitions of this part.

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

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

56.07. Corporation or Entity to Provide Patient with Copy of Medical Information, Profile or Summary Maintained

(a) Except as provided in subdivision (c), upon the patient's written request, any corporation described in Section 56.06, or any other entity that compiles or maintains medical information for any reason, shall provide the patient, at no charge, with a copy of any medical profile, summary, or information maintained by the corporation or entity with respect to the patient.

(b) A request by a patient pursuant to this section shall not be deemed to be an authorization by the patient for the release or disclosure of any information to any person or entity other than the patient.

(c) This section shall not apply to any patient records that are subject to inspection by the patient pursuant to Section 123110 of the Health and Safety Code and shall not be deemed to limit the right of a health care provider to charge a fee for the preparation of a summary of patient records as provided in Section 123130 of the Health and Safety Code. This section shall not apply to a health care service plan licensed pursuant to

Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer licensed pursuant to the Insurance Code. This section shall not apply to medical information compiled or maintained by a fire and casualty insurer or its retained counsel in the regular course of investigating or litigating a claim under a policy of insurance that it has written. For the purposes of this section, a fire and casualty insurer is an insurer writing policies that may be sold by a fire and casualty licensee pursuant to Section 1625 of the Insurance Code.

CHAPTER 2. DISCLOSURE OF MEDICAL INFORMATION BY PROVIDERS

56.10. Prohibition of Unauthorized Disclosure of Medical Information

(a) A provider of health care, health care service plan, or contractor shall not disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).

(b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:

(1)(A) A court order issued by a court of this state or a federal court, including, but not limited to, a court order issued by a court of this state pursuant to Section 2029.300 of the Code of Civil Procedure relating to a foreign subpoena.

(B) A provider of health care, health care service plan, or contractor shall not comply with a court order that constitutes a foreign subpoena, absent a court order issued pursuant to Section 2029.300 of the Code of Civil Procedure.

(2) A board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.

(3) A party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to Section 1987 of the Code of Civil

Procedure, or any provision authorizing discovery in a proceeding before a court or administrative agency.

(4) A board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.

(5) An arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under Section 1282.6 of the Code of Civil Procedure, or another provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

(6) A valid search warrant issued by a judicial officer, including a magistrate, to a governmental law enforcement agency, including a search warrant from another state that is based on either of the following and execution of the search warrant would not constitute a violation of Section 13778.2 of the Penal Code:

(A) Another state's law, so long as that state's law does not interfere with California law, including, but not limited to, the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code).

(B) A foreign penal civil action, as defined in Section 2029.200 of the Code of Civil Procedure.

(7) The patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) A medical examiner, forensic pathologist, or coroner, when requested in the course of an investigation by a medical examiner, forensic pathologist, or coroner's office for the purpose of identifying the decedent or locating next of kin, or when investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant deaths, suspicious deaths, unknown deaths, or criminal deaths, or upon notification of, or investigation of, imminent deaths that may involve organ or tissue donation pursuant to Section 7151.15 of the Health and

Safety Code, or when otherwise authorized by the decedent's representative. Medical information requested by a medical examiner, forensic pathologist, or coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation or who is the prospective donor and shall be disclosed to a medical examiner, forensic pathologist, or coroner without delay upon request. A medical examiner, forensic pathologist, or coroner shall not disclose the information contained in the medical record obtained pursuant to this paragraph to a third party without a court order or authorization pursuant to paragraph (4) of subdivision (c) of Section 56.11.

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and

to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to a person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, information so disclosed shall not be further disclosed by the recipient in a way that would violate this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of a provider of health care or a health care service plan may be reviewed by a private or public body responsible for licensing or accrediting the provider of health care or a health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in a way that would violate this part.

(6) The information may be disclosed to a medical examiner, forensic pathologist, or county coroner in the course of an investigation by a medical examiner, forensic pathologist, or coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b). A medical examiner, forensic pathologist, or coroner shall not disclose the information contained in the medical record obtained pursuant to this paragraph to a third party without a court order or authorization pursuant to paragraph (4) of subdivision (c) of Section 56.11.

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in a way that would disclose the identity of a patient or violate this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or a health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient

seeks coverage by or benefits from, if the information was created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information shall not otherwise be disclosed by a health care service plan except in accordance with this part.

(11) This part does not prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Chapter 1 of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all of the requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Chapter 1 of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition, care, and treatment provided may be disclosed to a probate court investigator in the course of an investigation required or authorized in a conservatorship proceeding under the Guardianship-Conservatorship Law as defined in Section 1400 of the Probate Code, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existing guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, "tissue bank"

and “tissue” have the same meanings as defined in Section 1635 of the Health and Safety Code.

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, including, but not limited to, the voluntary reporting, either directly or indirectly, to the United States Food and Drug Administration of adverse events related to drug products or medical device problems, or to disclosures made pursuant to subdivisions (b) and (c) of Section 11167 of the Penal Code by a person making a report pursuant to Sections 11165.9 and 11166 of the Penal Code, provided that those disclosures concern a report made by that person.

(15) Basic information, including the patient’s name, city of residence, age, sex, and general condition, may be disclosed to a state-recognized or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in a way that would violate this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to an entity contracting with a health care service plan or the health care service plan’s contractors to monitor or administer care of enrollees for a covered benefit, if the disease management services and care are authorized by a treating physician, or (B) to a disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, if the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care

service plan's or contractor's network of physicians. This paragraph does not require physician authorization for the care or treatment of the adherents of a well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(18) The information may be disclosed, as permitted by state and federal law or regulation, to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events, including, but not limited to, birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions, as authorized or required by state or federal law or regulation.

(19) The information may be disclosed, consistent with applicable law and standards of ethical conduct, by a psychotherapist, as defined in Section 1010 of the Evidence Code, if the psychotherapist, in good faith, believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a reasonably foreseeable victim or victims, and the disclosure is made to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

(20) The information may be disclosed as described in Section 56.103.

(21) (A) The information may be disclosed to an employee welfare benefit plan, as defined under Section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1002(1)), which is formed under Section 302(c)(5) of the Taft-Hartley Act (29 U.S.C. Sec. 186(c)(5)), to the extent that the employee welfare benefit plan provides medical care, and may also be disclosed to an entity contracting with the employee welfare benefit plan for billing, claims management, medical data processing, or other administrative services related to the provision of medical care to persons enrolled in the employee welfare benefit plan for health care coverage, if all of the following conditions are met:

(i) The disclosure is for the purpose of determining eligibility, coordinating benefits, or allowing the employee welfare benefit plan or the contracting entity to advocate on the behalf of a patient or enrollee with a provider, a health care service plan, or a state or federal regulatory agency.

(ii) The request for the information is accompanied by a written authorization for the release of the information submitted in a manner consistent with subdivision (a) and Section 56.11.

(iii) The disclosure is authorized by and made in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(iv) Any information disclosed is not further used or disclosed by the recipient in any way that would directly or indirectly violate this part or the restrictions imposed by Part 164 of Title 45 of the Code of Federal Regulations, including the manipulation of the information in any way that might reveal individually identifiable medical information.

(B) For purposes of this paragraph, Section 1374.8 of the Health and Safety Code shall not apply.

(22) Information may be disclosed pursuant to subdivision (a) of Section 15633.5 of the Welfare and Institutions Code by a person required to make a report pursuant to Section 15630 of the Welfare and Institutions Code, provided that the disclosure under subdivision (a) of Section 15633.5 concerns a report made by that person. Covered entities, as they are defined in Section 160.103 of Title 45 of the Code of Federal Regulations, shall comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule pursuant to subsection (c) of Section 164.512 of Title 45 of the Code of Federal Regulations if the disclosure is not for the purpose of public health surveillance, investigation, intervention, or reporting an injury or death.

(d) Except to the extent expressly authorized by a patient, enrollee, or subscriber, or as provided by subdivisions (b) and (c), a provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall not intentionally share, sell, use for marketing, or otherwise use

medical information for a purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by a patient or enrollee or subscriber or as provided by subdivisions (b) and (c), a contractor or corporation and its subsidiaries and affiliates shall not further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to a person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

(f) Except to the extent expressly authorized by a patient, enrollee, or subscriber, or as required by subdivision (b), or as permitted by subdivision (c), a provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall not disclose medical information for immigration enforcement.

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

(1) "Medical examiner, forensic pathologist, or coroner" means a coroner or deputy coroner, as described in subdivision (c) of Section 830.35 of the Penal Code, or a licensed physician who currently performs official autopsies on behalf of a county coroner's office or a medical examiner's office, whether as a government employee or under contract to that office.

(2) "School-linked services coordinator" means an individual located on a school campus or under contract by a county behavioral health provider agency for the treatment and health care operations and referrals of students and their families that holds any of the following:

(A) A services credential with a specialization in pupil personnel services, as described in Section 44266 of the Education Code.

(B) A services credential with a specialization in health authorizing service as a school nurse, as described in Section 44877 of the Education Code.

(C) A license to engage in the practice of marriage and family therapy issued pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code.
(D) A license to engage in the practice of educational psychology issued pursuant to Chapter 13.5 (commencing with Section 4989.10) of Division 2 of the Business and Professions Code.
(E) A license to engage in the practice of professional clinical counseling issued pursuant to Chapter 16 (commencing with Section 4999.10) of Division 2 of the Business and Professions Code.

56.1007. Authorized Disclosure of Medical Information

(a) A provider of health care, health care service plan, or contractor may, in accordance with subdivision (c) or (d), disclose to a family member, other relative, domestic partner, or a close personal friend of the patient, or any other person identified by the patient, the medical information directly relevant to that person's involvement with the patient's care or payment related to the patient's health care.

(b) A provider of health care, health care service plan, or contractor may use or disclose medical information to notify, or assist in the notification of, including identifying or locating, a family member, a personal representative of the patient, a domestic partner, or another person responsible for the care of the patient of the patient's location, general condition, or death. Any use or disclosure of medical information for those notification purposes shall be in accordance with the provisions of subdivision (c), (d), or (e), as applicable.

(c) (1) Except as provided in paragraph (2), if the patient is present for, or otherwise available prior to, a use or disclosure permitted by subdivision (a) or (b) and has the capacity to make health care decisions, the provider of health care, health care service plan, or contractor may use or disclose the medical information if it does any of the following:

(A) Obtains the patient's agreement.

(B) Provides the patient with the opportunity to object to the disclosure, and the patient does not express an objection.

(C) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the patient does not object to the disclosure.

(2) A provider of health care who is a psychotherapist, as defined in Section 1010 of the Evidence Code, may use or disclose medical information pursuant to this subdivision only if the psychotherapist complies with subparagraph (A) or (B) of paragraph (1).

(d) If the patient is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the patient's incapacity or an emergency circumstance, the provider of health care, health care service plan, or contractor may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the patient and, if so, disclose only the medical information that is directly relevant to the person's involvement with the patient's health care. A provider of health care, health care service plan, or contractor may use professional judgment and its experience with common practice to make reasonable inferences of the patient's best interest in allowing a person to act on behalf of the patient to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of medical information.

(e) A provider of health care, health care service plan, or contractor may use or disclose medical information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with those entities the uses or disclosures permitted by subdivision (b). The requirements in subdivisions (c) and (d) apply to those uses and disclosures to the extent that the provider of health care, health care service plan, or contractor, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(f) Nothing in this section shall be construed to interfere with or limit the access authority of Protection and Advocacy, Inc., the Office of Patients' Rights, or any county patients' rights advocates to access medical information pursuant to any state or federal law.

56.101. Protection of Electronic Medical Information Integrity; Record Changes Made to Electronic Medical Record

(a) Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall do so in a manner that preserves the confidentiality of the information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.

(b) (1) An electronic health record system or electronic medical record system shall do all of the following:

(A) Protect and preserve the integrity of electronic medical information.

(B) Automatically record and preserve any change or deletion of any electronically stored medical information. The record of any change or deletion shall include the identity of the person who accessed and changed the medical information, the date and time the medical information was accessed, and the change that was made to the medical information.

(2) A patient's right to access or receive a copy of the patient's electronic medical records upon request shall be consistent with applicable state and federal laws governing patient access to, and the use and disclosures of, medical information.

(c)(1) A business, as described in Section 56.06, that electronically stores or maintains medical information on the provision of sensitive services, including, but not limited to, on an electronic health record system or electronic medical record system, on behalf of a provider of health care, health care service plan, pharmaceutical company, contractor, or employer, shall develop capabilities, policies, and procedures, on or before July 1, 2024, to enable all of the following:

(A) Limit user access privileges to information systems that contain medical information related to gender affirming care,

abortion and abortion-related services, and contraception only to those persons who are authorized to access specified medical information.

(B) Prevent the disclosure, access, transfer, transmission, or processing of medical information related to gender affirming care, abortion and abortion-related services, and contraception to persons and entities outside of this state in accordance to this part.

(C) Segregate medical information related to gender affirming care, abortion and abortion-related services, and contraception from the rest of the patient's record.

(D) Provide the ability to automatically disable access to segregated medical information related to gender affirming care, abortion and abortion-related services, and contraception by individuals and entities in another state.

(2) Any fees charged to providers of health care, health care service plans, pharmaceutical company, contractors, employers, or patients to comply with this subdivision shall be consistent with Section 171.302 of Title 45 of the Code of Federal Regulations.

(3) For the purposes of this subdivision, "gender affirming care" means gender affirming health care and gender affirming mental health care as defined in subdivision (b) of Section 16010.2 of the Welfare and Institutions Code.

(4) This subdivision does not apply to a provider of health care, as defined in Section 56.05.

(d) This section shall apply to an "electronic medical record" or "electronic health record" that meets the definition of "electronic health record," as that term is defined in Section 17921(5) of Title 42 of the United States Code.

56.102. Disclosure of Medical Information to Pharmaceutical Company not Required; Exceptions

(a) A pharmaceutical company may not require a patient, as a condition of receiving pharmaceuticals, medications, or prescription drugs, to sign an authorization, release, consent, or waiver that would permit the disclosure of medical information

that otherwise may not be disclosed under Section 56.10 or any other provision of law, unless the disclosure is for one of the following purposes:

(1) Enrollment of the patient in a patient assistance program or prescription drug discount program.

(2) Enrollment of the patient in a clinical research project.

(3) Prioritization of distribution to the patient of a prescription medicine in limited supply in the United States.

(4) Response to an inquiry from the patient communicated in writing, by telephone, or by electronic mail.

(b) Except as provided in subdivision (a) or Section 56.10, a pharmaceutical company may not disclose medical information provided to it without first obtaining a valid authorization from the patient.

56.104. Standards for Disclosing Information Related to Outpatient Psychotherapy

(a) Notwithstanding subdivision (c) of Section 56.10, except as provided in subdivision (e), no provider of health care, health care service plan, or contractor may release medical information to persons or entities who have requested that information and who are authorized by law to receive that information pursuant to subdivision (c) of Section 56.10, if the requested information specifically relates to the patient's participation in outpatient treatment with a psychotherapist, unless the person or entity requesting that information submits to the patient pursuant to subdivision (b) and to the provider of health care, health care service plan, or contractor a written request, signed by the person requesting the information or an authorized agent of the entity requesting the information, that includes all of the following:

(1) The specific information relating to a patient's participation in outpatient treatment with a psychotherapist being requested and its specific intended use or uses.

(2) The length of time during which the information will be kept before being destroyed or disposed of. A person or entity may extend that timeframe, provided that the person or entity

notifies the provider, plan, or contractor of the extension. Any notification of an extension shall include the specific reason for the extension, the intended use or uses of the information during the extended time, and the expected date of the destruction of the information.

(3) A statement that the information will not be used for any purpose other than its intended use.

(4) A statement that the person or entity requesting the information will destroy the information and all copies in the person's or entity's possession or control, will cause it to be destroyed, or will return the information and all copies of it before or immediately after the length of time specified in paragraph (2) has expired.

(b) The person or entity requesting the information shall submit a copy of the written request required by this section to the patient within 30 days of receipt of the information requested, unless the patient has signed a written waiver in the form of a letter signed and submitted by the patient to the provider of health care or health care service plan waiving notification.

(c) For purposes of this section, "psychotherapist" means a person who is both a "psychotherapist" as defined in Section 1010 of the Evidence Code and a "provider of health care" as defined in Section 56.05.

(d) This section does not apply to the disclosure or use of medical information by a law enforcement agency or a regulatory agency when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes, unless the disclosure is otherwise prohibited by law.

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

(1) Information authorized to be disclosed pursuant to paragraph (1) of subdivision (c) of Section 56.10.

(2) Information requested from a psychotherapist by law enforcement or by the target of the threat subsequent to a disclosure by that psychotherapist authorized by paragraph (19) of subdivision (c) of Section 56.10, in which the additional information is clearly necessary to prevent the serious and imminent threat disclosed under that paragraph.

(3) Information disclosed by a psychotherapist pursuant to paragraphs (14) and (22) of subdivision (c) of Section 56.10 and requested by an agency investigating the abuse reported pursuant to those paragraphs.

(f) Nothing in this section shall be construed to grant any additional authority to a provider of health care, health care service plan, or contractor to disclose information to a person or entity without the patient's consent.

56.105. Disclosure of Records for Malpractice Suits

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

Notice of any request for medical information made pursuant to an authorization as provided by this section shall be given to the patient or the patient's legal representative. The notice shall describe the inclusive subject matter and dates of the materials

requested and shall also authorize the patient or the patient's legal representative to receive, upon request, copies of the information at his or her expense.

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

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

56.109.

(a) Notwithstanding subdivision (b) of Section 56.10, a provider of health care, health care service plan, or contractor shall not release medical information related to a person seeking or obtaining gender-affirming health care or gender-affirming mental health care or a person or entity allowing a child to receive gender-affirming health care or gender-affirming mental health care in response to any subpoena or request, including a foreign subpoena, based on another state's law that interferes with an individual's right to seek or obtain gender-affirming health care or gender-affirming mental health care or authorizes a person to bring a civil or criminal action against a person or entity that allows a child to receive gender-affirming health care or gender-affirming mental health care.

(b) Notwithstanding subdivision (c) of Section 56.10, a provider of health care, health care service plan, or contractor shall not release medical information to persons or entities who have requested that information and who are authorized by law to receive that information pursuant to subdivision (c) of Section 56.10, if the information is related to an individual seeking or

obtaining gender-affirming health care or gender-affirming mental health care or to a person or entity allowing a child to receive gender-affirming health care or gender-affirming mental health care, and the information is being requested pursuant to another state's law that authorizes a person to bring a civil or criminal action against a person or entity that provides, seeks, obtains, or receives gender-affirming health care or gender-affirming mental health care or who allows a child to receive gender-affirming health care or gender-affirming mental health care.

(c) Notwithstanding subdivisions (b) and (c) of Section 56.10 or subdivision (c) of Section 56.20, a provider of health care, health care service plan, contractor, or employer shall not cooperate with any inquiry or investigation by, or provide medical information to, any individual, agency, or department from another state or, to the extent permitted by federal law, to a federal law enforcement agency that would identify an individual and that is related to an individual seeking or obtaining gender-affirming health care or gender-affirming mental health care that is lawful under the laws of this state.

(d) This section does not prohibit compliance with the investigation of activity that is punishable as a crime under the laws of this state.

(e) This section does not prohibit compliance with an audit or investigation of activity that is unlawful under the laws of this state or federal law, or with an audit, review, or investigation conducted for purposes of licensure, registration, accreditation, or certification under the laws of this state or federal law or pursuant to an accrediting organization recognized by the State Department of Public Health or the federal Centers for Medicare and Medicaid Services.

(f) This section does not prohibit the Department of Corrections and Rehabilitation from disclosing medical information of an individual to a health care facility that is run by an agency or department from another state, or to a federal law enforcement agency, for treatment purposes and direct medical care for the specified individual and is narrowly limited to the request.

(g) For the purposes of this section, the following terms have the following meanings:
(1) “Gender-affirming health care” and “gender-affirming mental health care” shall have the same meanings as provided in Section 16010.2 of the Welfare and Institutions Code.
(2) “Person” means an individual or governmental subdivision, agency, or instrumentality.

56.110.
(a) Notwithstanding subdivision (c) of Section 56.10, a provider of health care, health care service plan, pharmaceutical company, contractor, or employer shall not knowingly disclose, transmit, transfer, share, or grant access to medical information in an electronic health records system or through a health information exchange that would identify an individual and that is related to an individual seeking, obtaining, providing, supporting, or aiding in the performance of an abortion that is lawful under the laws of this state to any individual or entity from another state, unless the disclosure, transmittal, transfer, sharing, or granting of access is authorized under any of the following conditions:
(1) In accordance with a valid, written authorization pursuant to Section 56.11 that clearly states that medical information on abortion or abortion-related services may be disclosed, and only to the extent and for the purposes expressly stated in the authorization.
(2) In accordance with paragraphs (2) and (3) of subdivision (c) of Section 56.10, to the extent necessary to allow responsibility for payment to be determined and payment to be made or to the extent that it is not further disclosed by the recipient in a way that would violate this part.
(3) In accordance with paragraphs (4) and (5) of subdivision (c) of Section 56.10 for the purpose of accreditation, in reviewing the competence or qualifications of health care professionals, or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.
(4) In accordance with paragraph (7) of subdivision (c) of Section 56.10, for the purpose of bona fide research. Institutional Review

Boards shall consider the potential harm to the patient and the patient's privacy when the research uses data that contains information related to abortion or abortion-related services and the research is performed out of state.
(b) Notwithstanding subdivision (a), the content of the health records containing medical information described in subdivision (a) shall be disclosed to any of the following:
(1) A patient, or their personal representative, consistent with the Patient Access to Health Records Act (Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code).
(2) In response to an order of a California or federal court, but only to the extent clearly stated in the order and consistent with Section 1543 of the Penal Code, if applicable, and only if all information about the patient's identity and records are protected from public scrutiny through mechanisms, including, but not limited to, a sealed proceeding or court record.
(3) When expressly required by federal law that preempts California law, but only to the extent expressly required.
(c) Nothing in this section shall prohibit a provider of health care, health care service plan, pharmaceutical company, contractor, or employer from cooperating or complying with the investigation of activity that is punishable as a crime under the laws of California, and that took place in California.
(d) A provider of health care, as defined in Section 56.05, shall not be subject to liability for damages or to civil or enforcement actions, including disciplinary actions, fines, or penalties, for failure to meet the requirements of this section before January 31, 2026, 2027, if the provider of health care is working diligently and in good faith to come into compliance with this section.

56.11. Standards for Authorizing Medical Information Disclosure

Any person or entity that wishes to obtain medical information pursuant to subdivision (a) of Section 56.10, other than a person or entity authorized to receive medical information pursuant to subdivision (b) or (c) of Section 56.10, except as provided in

paragraph (21) of subdivision (c) of Section 56.10, shall obtain a valid authorization for the release of this information.

An authorization for the release of medical information by a provider of health care, health care service plan, pharmaceutical company, or contractor shall be valid if it:

(a) Is handwritten by the person who signs it or is in a typeface no smaller than 14-point type.

(b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no other purpose than to execute the authorization.

(c) Is signed and dated by one of the following:

(1) The patient. A patient who is a minor may only sign an authorization for the release of medical information obtained by a provider of health care, health care service plan, pharmaceutical company, or contractor in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

(2) The legal representative of the patient, if the patient is a minor or an incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information obtained by the provider of health care, health care service plan, pharmaceutical company, or contractor in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

(3) The spouse of the patient or the person financially responsible for the patient, where the medical information is being sought for the sole purpose of processing an application for health insurance or for enrollment in a nonprofit hospital plan, a health care service plan, or an employee benefit plan, and where the patient is to be an enrolled spouse or dependent under the policy or plan.

(4) The beneficiary or personal representative of a deceased patient.

(d) States the specific uses and limitations on the types of medical information to be disclosed.

(e) States the name or functions of the provider of health care, health care service plan, pharmaceutical company, or contractor that may disclose the medical information.

(f) States the name or functions of the persons or entities authorized to receive the medical information.

(g) States the specific uses and limitations on the use of the medical information by the persons or entities authorized to receive the medical information.

(h) States a specific date after which the provider of health care, health care service plan, pharmaceutical company, or contractor is no longer authorized to disclose the medical information.

(i) Advises the person signing the authorization of the right to receive a copy of the authorization.

56.12. Requirement to Furnish Information

Upon demand by the patient or the person who signed an authorization, a provider of health care, health care service plan, pharmaceutical company, or contractor possessing the authorization shall furnish a true copy thereof.

56.13. Prohibition of Further Disclosure

A recipient of medical information pursuant to an authorization as provided by this chapter or pursuant to the provisions of subdivision (c) of Section 56.10 may not further disclose that medical information except in accordance with a new authorization that meets the requirements of Section 56.11, or as specifically required or permitted by other provisions of this chapter or by law.

56.14. Limitations on Use of Disclosed Information

A provider of health care, health care service plan, or contractor that discloses medical information pursuant to the authorizations required by this chapter shall communicate to the person or entity to which it discloses the medical information any limitations in the authorization regarding the use of the medical information. No provider of health care, health care service plan, or contractor that has attempted in good faith to comply with

this provision shall be liable for any unauthorized use of the medical information by the person or entity to which the provider, plan, or contractor disclosed the medical information.

56.15. Patient's Right to Cancel or Modify Disclosure Authorization

Nothing in this part shall be construed to prevent a person who could sign the authorization pursuant to subdivision (c) of Section 56.11 from cancelling or modifying an authorization. However, the cancellation or modification shall be effective only after the provider of health care actually receives written notice of the cancellation or modification.

56.16. Information Providers May Disclose Without Authorization

For disclosures not addressed by Section 56.1007, unless there is a specific written request by the patient to the contrary, nothing in this part shall be construed to prevent a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, upon an inquiry concerning a specific patient, from releasing at its discretion any of the following information: the patient's name, address, age, and sex; a general description of the reason for treatment (whether an injury, a burn, poisoning, or some unrelated condition); the general nature of the injury, burn, poisoning, or other condition; the general condition of the patient; and any information that is not medical information as defined in Section 56.05.

CHAPTER 6. RELATIONSHIP TO EXISTING LAW

56.30. Exceptions to the Act

The disclosure and use of the following medical information shall not be subject to the limitations of this part:

(a) (Mental health and developmental disabilities) Information and records obtained in the course of providing services under Division 4 (commencing with Section 4000), Division 4.1

(commencing with Section 4400), Division 4.5 (commencing with Section 4500), Division 5 (commencing with Section 5000), Division 6 (commencing with Section 6000), or Division 7 (commencing with Section 7100) of the Welfare and Institutions Code.

(b) (Public social services) Information and records that are subject to Sections 10850, 14124.1, and 14124.2 of the Welfare and Institutions Code.

(c) (State health services, communicable diseases, developmental disabilities) Information and records maintained pursuant to former Chapter 2 (commencing with Section 200) of Part 1 of Division 1 of the Health and Safety Code and pursuant to the Communicable Disease Prevention and Control Act (subdivision (a) of Section 27 of the Health and Safety Code).

(d) (Licensing and statistics) Information and records maintained pursuant to Division 2 (commencing with Section 1200) and Part 1 (commencing with Section 102100) of Division 102 of the Health and Safety Code; pursuant to Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code; and pursuant to Section 8608, 8817, or 8909 of the Family Code.

(e) (Medical survey, workers' safety) Information and records acquired and maintained or disclosed pursuant to Sections 1380 and 1382 of the Health and Safety Code and pursuant to Division 5 (commencing with Section 6300) of the Labor Code.

(f) (Industrial accidents) Information and records acquired, maintained, or disclosed pursuant to Division 1 (commencing with Section 50), Division 4 (commencing with Section 3200), Division 4.5 (commencing with Section 6100), and Division 4.7 (commencing with Section 6200) of the Labor Code.

(g) (Law enforcement) Information and records maintained by a health facility which are sought by a law enforcement agency under Chapter 3.5 (commencing with Section 1543) of Title 12 of Part 2 of the Penal Code.

(h) (Investigations of employment accident or illness) Information and records sought as part of an investigation of an on-the-job accident or illness pursuant to Division 5 (commencing

with Section 6300) of the Labor Code or pursuant to Section 105200 of the Health and Safety Code.

(i) (Alcohol or drug abuse) Information and records subject to the federal alcohol and drug abuse regulations (Part 2 (commencing with Section 2.1) of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations) or to Section 11845.5 of the Health and Safety Code dealing with alcohol and drug abuse.

(j) (Patient discharge data) Nothing in this part shall be construed to limit, expand, or otherwise affect the authority of the California Health Facilities Commission to collect patient discharge information from health facilities.

(k) Medical information and records disclosed to, and their use by, the Insurance Commissioner, the Director of the Department of Managed Health Care, the Division of Industrial Accidents, the Workers' Compensation Appeals Board, the Department of Insurance, or the Department of Managed Health Care.

(l) Medical information and records related to services provided on and after January 1, 2006, disclosed to, and their use by, the Managed Risk Medical Insurance Board to the same extent that those records are required to be provided to the board related to services provided on and after July 1, 2009, to comply with Section 403 of the federal Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111-3), applying subdivision (c) of Section 1932 of the federal Social Security Act.

56.31. Disclosure of Patient Information Related to HIV Prohibited without Authorization

Notwithstanding any other provision of law, nothing in subdivision (f) of Section 56.30 shall permit the disclosure or use of medical information regarding whether a patient is infected with or exposed to the human immunodeficiency virus without the prior authorization from the patient unless the patient is an injured worker claiming to be infected with or exposed to the human immunodeficiency virus through an exposure incident arising out of and in the course of employment.

CHAPTER 7. VIOLATIONS

56.35. Limitation on Damage Awards and Attorney Fee Awards

In addition to any other remedies available at law, a patient whose medical information has been used or disclosed in violation of Section 56.10 or 56.104 or 56.20 or subdivision (a) of Section 56.26 and who has sustained economic loss or personal injury therefrom may recover compensatory damages, punitive damages not to exceed three thousand dollars ($3,000), attorneys' fees not to exceed one thousand dollars ($1,000), and the costs of litigation.

56.36. Penalties

(a) A violation of the provisions of this part that results in economic loss or personal injury to a patient is punishable as a misdemeanor.

(b) In addition to any other remedies available at law, an individual may bring an action against a person or entity who has negligently released confidential information or records concerning him or her in violation of this part, for either or both of the following:

(1) Except as provided in subdivision (e), nominal damages of one thousand dollars ($1,000). In order to recover under this paragraph, it is not necessary that the plaintiff suffered or was threatened with actual damages.

(2) The amount of actual damages, if any, sustained by the patient.

(c) (1) In addition, a person or entity that negligently discloses medical information in violation of the provisions of this part shall also be liable, irrespective of the amount of damages suffered by the patient as a result of that violation, for an administrative fine or civil penalty not to exceed two thousand five hundred dollars ($2,500) per violation.

(2) (A) A person or entity, other than a licensed health care professional, who knowingly and willfully obtains, discloses, or uses medical information in violation of this part shall be liable

for an administrative fine or civil penalty not to exceed twenty-five thousand dollars ($25,000) per violation.

(B) A licensed health care professional who knowingly and willfully obtains, discloses, or uses medical information in violation of this part shall be liable on a first violation for an administrative fine or civil penalty not to exceed two thousand five hundred dollars ($2,500) per violation, on a second violation for an administrative fine or civil penalty not to exceed ten thousand dollars ($10,000) per violation, or on a third and subsequent violation for an administrative fine or civil penalty not to exceed twenty-five thousand dollars ($25,000) per violation. This subdivision shall not be construed to limit the liability of a health care service plan, a contractor, or a provider of health care that is not a licensed health care professional for a violation of this part.

(3) (A) A person or entity, other than a licensed health care professional, who knowingly or willfully obtains or uses medical information in violation of this part for the purpose of financial gain shall be liable for an administrative fine or civil penalty not to exceed two hundred fifty thousand dollars ($250,000) per violation and shall also be subject to disgorgement of any proceeds or other consideration obtained as a result of the violation.

(B) A licensed health care professional who knowingly and willfully obtains, discloses, or uses medical information in violation of this part for financial gain shall be liable on a first violation for an administrative fine or civil penalty not to exceed five thousand dollars ($5,000) per violation, on a second violation for an administrative fine or civil penalty not to exceed twenty-five thousand dollars ($25,000) per violation, or on a third and subsequent violation for an administrative fine or civil penalty not to exceed two hundred fifty thousand dollars ($250,000) per violation and shall also be subject to disgorgement of any proceeds or other consideration obtained as a result of the violation. This subdivision shall not be construed to limit the liability of a health care service plan, a contractor, or a provider

of health care that is not a licensed health care professional for any violation of this part.

(4) This subdivision shall not be construed as authorizing an administrative fine or civil penalty under both paragraphs (2) and (3) for the same violation.

(5) A person or entity who is not permitted to receive medical information pursuant to this part and who knowingly and willfully obtains, discloses, or uses medical information without written authorization from the patient shall be liable for a civil penalty not to exceed two hundred fifty thousand dollars ($250,000) per violation.

(d) In assessing the amount of an administrative fine or civil penalty pursuant to subdivision (c), the State Department of Public Health, licensing agency, or certifying board or court shall consider any of the relevant circumstances presented by any of the parties to the case including, but not limited to, the following:

(1) Whether the defendant has made a reasonable, good faith attempt to comply with this part.

(2) The nature and seriousness of the misconduct.

(3) The harm to the patient, enrollee, or subscriber.

(4) The number of violations.

(5) The persistence of the misconduct.

(6) The length of time over which the misconduct occurred.

(7) The willfulness of the defendant's misconduct.

(8) The defendant's assets, liabilities, and net worth.

(e) (1) In an action brought by an individual pursuant to subdivision (b) on or after January 1, 2013, in which the defendant establishes the affirmative defense in paragraph (2), the court shall award any actual damages and reasonable attorney's fees and costs, but shall not award nominal damages for a violation of this part.

(2) The defendant is entitled to an affirmative defense if all of the following are established, subject to the equitable considerations in paragraph (3):

(A) The defendant is a covered entity or business associate, as defined in Section 160.103 of Title 45 of the Code of Federal Regulations, in effect as of January 1, 2012.

(B) The defendant has complied with any obligations to notify all persons entitled to receive notice regarding the release of the information or records.

(C) The release of confidential information or records was solely to another covered entity or business associate.

(D) The release of confidential information or records was not an incident of medical identity theft. For purposes of this subparagraph, "medical identity theft" means the use of an individual's personal information, as defined in Section 1798.80, without the individual's knowledge or consent, to obtain medical goods or services, or to submit false claims for medical services.

(E) The defendant took appropriate preventive actions to protect the confidential information or records against release consistent with the defendant's obligations under this part or other applicable state law and the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) (HIPAA) and all HIPAA Administrative Simplification Regulations in effect on January 1, 2012, contained in Parts 160, 162, and 164 of Title 45 of the Code of Federal Regulations, and Part 2 of Title 42 of the Code of Federal Regulations, including, but not limited to, all of the following:

(i) Developing and implementing security policies and procedures.

(ii) Designating a security official who is responsible for developing and implementing its security policies and procedures, including educating and training the workforce.

(iii) Encrypting the information or records, and protecting against the release or use of the encryption key and passwords, or transmitting the information or records in a manner designed to provide equal or greater protections against improper disclosures.

(F) The defendant took reasonable and appropriate corrective action after the release of the confidential information or records, and the covered entity or business associate that

received the confidential information or records destroyed or returned the confidential information or records in the most expedient time possible and without unreasonable delay, consistent with any measures necessary to determine the scope of the breach and restore the reasonable integrity of the data system. A court may consider this subparagraph to be established if the defendant shows in detail that the covered entity or business associate could not destroy or return the confidential information or records because of the technology utilized.

(G) The covered entity or business associate that received the confidential information or records, or any of its agents, independent contractors, or employees, regardless of the scope of the employee's employment, did not retain, use, or release the information or records.

(H) After the release of the confidential information or records, the defendant took reasonable and appropriate action to prevent a future similar release of confidential information or records.

(I) The defendant has not previously established an affirmative defense pursuant to this subdivision, or the court determines, in its discretion, that application of the affirmative defense is compelling and consistent with the purposes of this section to promote reasonable conduct in light of all the facts.

(3) (A) In determining whether the affirmative defense may be established pursuant to paragraph (2), the court shall consider the equity of the situation, including, but not limited to, (i) whether the defendant has previously violated this part, regardless of whether an action has previously been brought, and (ii) the nature of the prior violation.

(B) To the extent the court allows discovery to determine whether there has been any other violation of this part that the court will consider in balancing the equities, the defendant shall not provide any medical information, as defined in Section 56.05. The court, in its discretion, may enter a protective order prohibiting the further use of any personal information, as defined in Section 1798.80, about the individual whose medical information may have been disclosed in a prior violation.

(4) In an action under this subdivision in which the defendant establishes the affirmative defense pursuant to paragraph (2), a plaintiff shall be entitled to recover reasonable attorney's fees and costs without regard to an award of actual or nominal damages or the imposition of administrative fines or civil penalties.

(5) In an action brought by an individual pursuant to subdivision (b) on or after January 1, 2013, in which the defendant establishes the affirmative defense pursuant to paragraph (2), a defendant shall not be liable for more than one judgment on the merits under this subdivision for releases of confidential information or records arising out of the same event, transaction, or occurrence.

(f) (1) The civil penalty pursuant to subdivision (c) shall be assessed and recovered in a civil action brought in the name of the people of the State of California in any court of competent jurisdiction by any of the following:

(A) The Attorney General.

(B) A district attorney.

(C) A county counsel authorized by agreement with the district attorney in actions involving violation of a county ordinance.

(D) A city attorney of a city.

(E) A city attorney of a city and county having a population in excess of 750,000, with the consent of the district attorney.

(F) A city prosecutor in a city having a full-time city prosecutor or, with the consent of the district attorney, by a city attorney in a city and county.

(G) The State Public Health Officer, or his or her designee, may recommend that a person described in subparagraphs (A) to (F), inclusive, bring a civil action under this section.

(2) If the action is brought by the Attorney General, one-half of the penalty collected shall be paid to the treasurer of the county in which the judgment was entered, and one-half to the General Fund. If the action is brought by a district attorney or county counsel, the penalty collected shall be paid to the treasurer of the county in which the judgment was entered. Except as provided in paragraph (3), if the action is brought by a city

attorney or city prosecutor, one-half of the penalty collected shall be paid to the treasurer of the city in which the judgment was entered and one-half to the treasurer of the county in which the judgment was entered.

(3) If the action is brought by a city attorney of a city and county, the entire amount of the penalty collected shall be paid to the treasurer of the city and county in which the judgment was entered.

(4) This section shall not be construed as authorizing both an administrative fine and civil penalty for the same violation.

(5) Imposition of a fine or penalty provided for in this section shall not preclude imposition of other sanctions or remedies authorized by law.

(6) Administrative fines or penalties issued pursuant to Section 1280.15 of the Health and Safety Code shall offset any other administrative fine or civil penalty imposed under this section for the same violation.

(g) For purposes of this section, "knowing" and "willful" shall have the same meanings as in Section 7 of the Penal Code.

(h) A person who discloses protected medical information in accordance with the provisions of this part is not subject to the penalty provisions of this part.

56.37. Requiring Patient to Authorize Disclosure of Information as Condition for Service is Prohibited

(a) No provider of health care, health care service plan, or contractor may require a patient, as a condition of receiving health care services, to sign an authorization, release, consent, or waiver that would permit the disclosure of medical information that otherwise may not be disclosed under Section 56.10 or any other provision of law. However, a health care service plan or disability insurer may require relevant enrollee or subscriber medical information as a condition of the medical underwriting process, provided that Sections 1374.7 and 1389.1 of the Health and Safety Code are strictly observed.

(b) Any waiver by a patient of the provisions of this part, except as authorized by Section 56.11 or 56.21 or subdivision (b) of

Section 56.26, shall be deemed contrary to public policy and shall be unenforceable.

Civil Code
Division 3, Part 4

PART 4. OBLIGATIONS ARISING FROM PARTICULAR TRANSACTIONS

Section

1798.29. Security Breach Notification
1798.82. Security Breach Notification

Title 1.8. Personal Data

1798.29. Computerized Data; Security Breach Notification Requirements

(a) Any agency that owns or licenses computerized data that includes personal information shall disclose any breach of the security of the system following discovery or notification of the breach in the security of the data to any resident of California whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person. The disclosure shall be made in the most expedient time possible and without unreasonable delay, consistent with the legitimate needs of law enforcement, as provided in subdivision (c), or any measures necessary to determine the scope of the breach and restore the reasonable integrity of the data system.

(b) Any agency that maintains computerized data that includes personal information that the agency does not own shall notify the owner or licensee of the information of any breach of the security of the data immediately following discovery, if the personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

(c) The notification required by this section may be delayed if a law enforcement agency determines that the notification will impede a criminal investigation. The notification required by this section shall be made after the law enforcement agency determines that it will not compromise the investigation.

(d) Any agency that is required to issue a security breach notification pursuant to this section shall meet all of the following requirements:

(1) The security breach notification shall be written in plain language, shall be titled "Notice of Data Breach," and shall present the information described in paragraph (2) under the following headings: "What Happened," "What Information Was Involved," "What We Are Doing," "What You Can Do," and "For More Information." Additional information may be provided as a supplement to the notice.

(A) The format of the notice shall be designed to call attention to the nature and significance of the information it contains.

(B) The title and headings in the notice shall be clearly and conspicuously displayed.

(C) The text of the notice and any other notice provided pursuant to this section shall be no smaller than 10-point type.

(D) For a written notice described in paragraph (1) of subdivision (i), use of the model security breach notification form prescribed below or use of the headings described in this paragraph with the information described in paragraph (2), written in plain language, shall be deemed to be in compliance with this subdivision. [Refer to statutory language for table contents – http://www.leginfo.legislature.ca.gov]

(E) For an electronic notice described in paragraph (2) of subdivision (i), use of the headings described in this paragraph with the information described in paragraph (2), written in plain language, shall be deemed to be in compliance with this subdivision.

(2) The security breach notification described in paragraph (1) shall include, at a minimum, the following information:

(A) The name and contact information of the reporting agency subject to this section.

(B) A list of the types of personal information that were or are reasonably believed to have been the subject of a breach.

(C) If the information is possible to determine at the time the notice is provided, then any of the following: (i) the date of the breach, (ii) the estimated date of the breach, or (iii) the date range within which the breach occurred. The notification shall also include the date of the notice.

(D) Whether the notification was delayed as a result of a law enforcement investigation, if that information is possible to determine at the time the notice is provided.

(E) A general description of the breach incident, if that information is possible to determine at the time the notice is provided.

(F) The toll-free telephone numbers and addresses of the major credit reporting agencies, if the breach exposed a social security number or a driver's license or California identification card number.

(3) At the discretion of the agency, the security breach notification may also include any of the following:

(A) Information about what the agency has done to protect individuals whose information has been breached.

(B) Advice on steps that the person whose information has been breached may take to protect himself or herself.

(e) Any agency that is required to issue a security breach notification pursuant to this section to more than 500 California residents as a result of a single breach of the security system shall electronically submit a single sample copy of that security breach notification, excluding any personally identifiable information, to the Attorney General. A single sample copy of a security breach notification shall not be deemed to be within subdivision (f) of Section 6254 of the Government Code.

(f) For purposes of this section, "breach of the security of the system" means unauthorized acquisition of computerized data that compromises the security, confidentiality, or integrity of personal information maintained by the agency. Good faith acquisition of personal information by an employee or agent of the agency for the purposes of the agency is not a breach of the

security of the system, provided that the personal information is not used or subject to further unauthorized disclosure.

(g) For purposes of this section, “personal information” means either of the following:

(1) An individual’s first name or first initial and last name in combination with any one or more of the following data elements, when either the name or the data elements are not encrypted:

(A) Social security number.

(B) Driver’s license number or California identification card number.

(C) Account number, credit or debit card number, in combination with any required security code, access code, or password that would permit access to an individual’s financial account.

(D) Medical information.

(E) Health insurance information.

(F) Information or data collected through the use or operation of an automated license plate recognition system, as defined in Section 1798.90.5.

(2) A user name or email address, in combination with a password or security question and answer that would permit access to an online account.

(h) (1) For purposes of this section, “personal information” does not include publicly available information that is lawfully made available to the general public from federal, state, or local government records.

(2) For purposes of this section, “medical information” means any information regarding an individual’s medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional.

(3) For purposes of this section, “health insurance information” means an individual’s health insurance policy number or subscriber identification number, any unique identifier used by a health insurer to identify the individual, or any information in an individual’s application and claims history, including any appeals records.

(4) For purposes of this section, “encrypted” means rendered unusable, unreadable, or indecipherable to an unauthorized person through a security technology or methodology generally accepted in the field of information security.

(i) For purposes of this section, “notice” may be provided by one of the following methods:

(1) Written notice.

(2) Electronic notice, if the notice provided is consistent with the provisions regarding electronic records and signatures set forth in Section 7001 of Title 15 of the United States Code.

(3) Substitute notice, if the agency demonstrates that the cost of providing notice would exceed two hundred fifty thousand dollars ($250,000), or that the affected class of subject persons to be notified exceeds 500,000, or the agency does not have sufficient contact information. Substitute notice shall consist of all of the following:

(A) Email notice when the agency has an email address for the subject persons.

(B) Conspicuous posting, for a minimum of 30 days, of the notice on the agency’s Internet Web site page, if the agency maintains one. For purposes of this subparagraph, conspicuous posting on the agency’s Internet Web site means providing a link to the notice on the home page or first significant page after entering the Internet Web site that is in larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks that call attention to the link.

(C) Notification to major statewide media and the Office of Information Security within the Department of Technology.

(4) In the case of a breach of the security of the system involving personal information defined in paragraph (2) of subdivision (g) for an online account, and no other personal information defined in paragraph (1) of subdivision (g), the agency may comply with this section by providing the security breach notification in electronic or other form that directs the person whose personal information has been breached to promptly change his or her

password and security question or answer, as applicable, or to take other steps appropriate to protect the online account with the agency and all other online accounts for which the person uses the same user name or email address and password or security question or answer.

(5) In the case of a breach of the security of the system involving personal information defined in paragraph (2) of subdivision (g) for login credentials of an email account furnished by the agency, the agency shall not comply with this section by providing the security breach notification to that email address, but may, instead, comply with this section by providing notice by another method described in this subdivision or by clear and conspicuous notice delivered to the resident online when the resident is connected to the online account from an Internet Protocol address or online location from which the agency knows the resident customarily accesses the account.

(j) Notwithstanding subdivision (i), an agency that maintains its own notification procedures as part of an information security policy for the treatment of personal information and is otherwise consistent with the timing requirements of this part shall be deemed to be in compliance with the notification requirements of this section if it notifies subject persons in accordance with its policies in the event of a breach of security of the system.

(k) Notwithstanding the exception specified in paragraph (4) of subdivision (b) of Section 1798.3, for purposes of this section, "agency" includes a local agency, as defined in subdivision (a) of Section 6252 of the Government Code.

Corporations Code
Title 1, Division 3, Part 14

PART 14. Retail Grocery Firms and Retail Drug Firms

Section

Section 14700. General provisions; definitions
Section 14701. Notice

Section 14702. Rulemaking authority
Section 14703. Stay of acquisition
Section 14704. Acquisitions subject to federal law
Section 14706. Right to bring action
Section 14707. Failure to provide notice

14700. General provisions; definitions

(a) No person shall acquire, directly or indirectly, any voting securities or assets of a retail grocery firm or retail drug firm unless both parties give, or in the case of a tender offer, the acquiring party gives, written notice to the Attorney General in accordance with this part.

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

(1) "Acquiring party" means a person by whom or on whose behalf the merger or other acquisition of control is to be effected and is either of the following:

(A) Is required to provide notice of the merger or acquisition to the Federal Trade Commission or the United States Department of Justice pursuant to the federal Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. Sec. 18a).

(B) Is acquiring more than a total of 20 retail drug firms or retail grocery firms.

(2) "Retail drug firm" means a person, as defined in Section 18 of the Labor Code, including a proprietorship, joint venture, corporate officer or executive, that has one or more businesses or establishments located within the state and is identified as a retail business or establishment in the North American Industry Classification System within the retail trade category 45611.

(3) "Retail grocery firm" means a person, as defined in Section 18 of the Labor Code, including a proprietorship, joint venture, corporate officer or executive, that has one or more businesses or establishments located within the state and is identified as a retail business or establishment in the North American Industry Classification System within the retail trade category 44511 and 455211.

14701. Notice

(a) The written notice shall be filed with the Attorney General no less than 180 days before the acquisition is made effective. The notice shall be made under oath or affirmation, and shall comply with the requirements of subdivision (c).

(b) If any transaction requiring written notice pursuant to this subdivision commences before the effective date of this section, the written notice shall be given to the Attorney General within 30 days before the transaction is made effective. Upon receiving notice, the Attorney General has 180 days to evaluate the transaction, during which time the effective date of the transaction shall be tolled. If any material change occurs in the facts set forth in the written notice filed with the Attorney General, an amendment setting forth the change and copies of all documents and other material relevant to the change shall be filed with the Attorney General within two business days after the amendment is made by, or provided to, the acquiring party.

(c) The notice required to be given to the Attorney General shall comply with either of the following:

(1) If the acquiring party is required to file notice with the Federal Trade Commission or the United States Department of Justice pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. Sec. 18a), the notice shall contain the same form and additional documentary material required under that act and any implementing regulations under that act.

(2) If the acquiring party is not required to file notice with the Federal Trade Commission or the United States Department of Justice, as specified in paragraph (1), the notice shall contain all of the following information:

(A) The name and address of each acquiring party and a report of the nature of its business operations during the past five years or for a lesser period if the person and their predecessors have been in existence less than five years.

(B) An informative description of the business intended to be done by the person and the person's subsidiaries, including, but not limited to, documents concerning its business or corporate structure, governance, or management.

(C) A list of all individuals who are or have been selected to become directors or executive officers or who perform or will perform functions appropriate to the positions.
(D) The source, nature, and amount of the consideration used or to be used in effecting the merger or other acquisition of control, a description of any transaction in which funds were or are to be obtained, including any pledge of the drug or grocery retail firm's stock or the stock of any of its subsidiaries or controlling affiliates, and the identity of persons furnishing the consideration. If a source of the consideration is a loan made in the lender's ordinary course of business, the identity of the lender shall remain confidential upon request of the person filing the statement.
(E) Fully audited financial information as to the earnings and financial condition of each acquiring party for the preceding five fiscal years or for a lesser period if the acquiring party and its predecessors have been in existence for less than five years, and similar unaudited information as of a date not earlier than 90 days before the written notice.
(F) Any plans or proposals that an acquiring party may have to liquidate the retail grocery or retail drug firms, to sell its assets or merge or consolidate it with any person, or to make any other material change in its business or corporate structure or management.
(G) The information required to assess the competitive effects of the proposed acquisition, giving particular attention to the effects on the proposed chain retail grocery store acquisition on consumers, including, but not limited to, consumer choice, food pricing, access to food, and food deserts, and factors affecting the supply of experienced grocery workers, including wages, benefits, and unemployment and chain retail pharmacy on patients, including, but not limited to, patient choice, medicine pricing, access to medications, and factors affecting the supply of licensed pharmacists, pharmacy technicians, and pharmacists-in-charge.
(H) Information required to assess the economic and community impact of any planned divestiture or store closures, including, but

not limited to, the impact on food deserts, food supply, economic mobility, unemployment, and small businesses.
(d) The Attorney General shall charge the acquiring party a filing fee for the cost to the Attorney General to receive, review, and analyze any notice under this section, which shall not exceed the reasonable regulatory costs to the Attorney General incident to performing its administrative duties under this section. The fee shall be based on the size of the transaction as of the date of the filing of the notice, but shall not exceed .00045 percent of the combined sales of the parties to the merger or acquisition for the fiscal year prior to the filing of the notice.
(e) The Attorney General may use the notice, documents, and information disclosed under to this section in a judicial action in state or federal court or an administrative action involving the merger or acquisition.

14702. Rulemaking authority
(a) The Attorney General may adopt regulations to effectuate this part that are necessary or appropriate for the protection of workers, consumers, and the public interest.
(b) The regulations may specify exemptions from the notice requirement for acquisitions that, by virtue of the size, business volume, or number of employees are unlikely to materially affect competitive markets in California.
(c) The regulations may authorize the Attorney General to request additional materials.
(d) The regulations may authorize adjustments in the filing fee, based on the size of the transaction, subject to the maximum amount set forth in subdivision (d) of Section 14701.

14703. Stay of acquisition
If the Attorney General determines that they cannot complete an evaluation of the competitive effects of the acquisition before the parties intend to consummate the acquisition, the Attorney General may seek an order from the Superior Court of the County of Sacramento temporarily staying or preliminarily enjoining the

acquisition for such time as is reasonably necessary for the Attorney General to complete the analysis.

14704. Acquisitions subject to federal law

(a) For acquisitions to which Section 18a of Title 15 of the United States Code applies, the Attorney General shall consider the extent to which information required to be submitted to the United States Department of Justice and the Federal Trade Commission may satisfy some or all of the need to carry out the applicable state laws. Any information that has been submitted to the Attorney General under provisions of federal law rendering them confidential shall be deemed to be confidential under California law.

(b) The submitting party may designate information submitted pursuant to this part as privileged or confidential. If the Attorney General disputes any claim of privilege or confidentiality, the Attorney General may give notice to the submitting party of that fact and give the submitting party, or other person interested in the claim of privilege or confidentiality, an opportunity to seek an order from the Superior Court of the County of Sacramento requiring the Attorney General not to make the designated information public. Except for information that the Attorney General agrees is privileged or confidential, or the court so determines, the information shall be available to the public under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code).

(c) The Attorney General may disclose any notice and information filed under this part to the attorney general of any other state, the Federal Trade Commission, the United States Department of Justice, or to another state agency, as long as that other state attorney general, state agency, or federal agency operates under a law substantially similar to this statute to guarantee the privileged or confidential nature of the notice and information disclosed.

14706. Right to bring action

Nothing in this section or any other law shall preclude the Attorney General or any person from bringing an action pursuant to this article or any other law to enjoin or seek divestiture of assets or ownership interests obtained in a completed acquisition or otherwise to restore competition.

14707. Failure to provide notice

(a) The failure to provide written notice, amendment to written notice, or other material required to be provided pursuant to this part shall be a violation of this part.

(b) In addition to any legal remedies the Attorney General may have, the Attorney General shall be entitled to injunctive relief and other equitable remedies a court deems appropriate for a violation of this part, shall be entitled to recover its attorney's fees and costs incurred in remedying each violation, and shall be entitled to civil penalties of up to twenty thousand dollars ($20,000) for each day of noncompliance with the requirements of Section 14700.

1798.82 Security Breach Notification Requirements

(a) A person or business that conducts business in California, and that owns or licenses computerized data that includes personal information, shall disclose a breach of the security of the system following discovery or notification of the breach in the security of the data to a resident of California whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person. The disclosure shall be made in the most expedient time possible and without unreasonable delay, consistent with the legitimate needs of law enforcement, as provided in subdivision (c), or any measures necessary to determine the scope of the breach and restore the reasonable integrity of the data system.

(b) A person or business that maintains computerized data that includes personal information that the person or business does not own shall notify the owner or licensee of the information of the breach of the security of the data immediately following discovery, if the personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

(c) The notification required by this section may be delayed if a law enforcement agency determines that the notification will impede a criminal investigation. The notification required by this section shall be made promptly after the law enforcement agency determines that it will not compromise the investigation.

(d) A person or business that is required to issue a security breach notification pursuant to this section shall meet all of the following requirements:

(1) The security breach notification shall be written in plain language, shall be titled “Notice of Data Breach,” and shall present the information described in paragraph (2) under the following headings: “What Happened,” “What Information Was Involved,” “What We Are Doing,” “What You Can Do,” and “For More Information.” Additional information may be provided as a supplement to the notice.

(A) The format of the notice shall be designed to call attention to the nature and significance of the information it contains.

(B) The title and headings in the notice shall be clearly and conspicuously displayed.

(C) The text of the notice and any other notice provided pursuant to this section shall be no smaller than 10-point type.

(D) For a written notice described in paragraph (1) of subdivision (j), use of the model security breach notification form prescribed below or use of the headings described in this paragraph with the information described in paragraph (2), written in plain language, shall be deemed to be in compliance with this subdivision.

[Refer to statutory language for table contents – http://www.leginfo.legislature.ca.gov]

(E) For an electronic notice described in paragraph (2) of subdivision (j), use of the headings described in this paragraph with the information described in paragraph (2), written in plain language, shall be deemed to be in compliance with this subdivision.

(2) The security breach notification described in paragraph (1) shall include, at a minimum, the following information:

(A) The name and contact information of the reporting person or business subject to this section.

(B) A list of the types of personal information that were or are reasonably believed to have been the subject of a breach.

(C) If the information is possible to determine at the time the notice is provided, then any of the following: (i) the date of the breach, (ii) the estimated date of the breach, or (iii) the date range within which the breach occurred. The notification shall also include the date of the notice.

(D) Whether notification was delayed as a result of a law enforcement investigation, if that information is possible to determine at the time the notice is provided.

(E) A general description of the breach incident, if that information is possible to determine at the time the notice is provided.

(F) The toll-free telephone numbers and addresses of the major credit reporting agencies if the breach exposed a social security

number or a driver's license or California identification card number.

(G) If the person or business providing the notification was the source of the breach, an offer to provide appropriate identity theft prevention and mitigation services, if any, shall be provided at no cost to the affected person for not less than 12 months along with all information necessary to take advantage of the offer to any person whose information was or may have been breached if the breach exposed or may have exposed personal information defined in subparagraphs (A) and (B) of paragraph (1) of subdivision (h).

(3) At the discretion of the person or business, the security breach notification may also include any of the following:

(A) Information about what the person or business has done to protect individuals whose information has been breached.

(B) Advice on steps that the person whose information has been breached may take to protect himself or herself.

(e) A covered entity under the federal Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Sec. 1320d et seq.) will be deemed to have complied with the notice requirements in subdivision (d) if it has complied completely with Section 13402(f) of the federal Health Information Technology for Economic and Clinical Health Act (Public Law 111-5). However, nothing in this subdivision shall be construed to exempt a covered entity from any other provision of this section.

(f) A person or business that is required to issue a security breach notification pursuant to this section to more than 500 California residents as a result of a single breach of the security system shall electronically submit a single sample copy of that security breach notification, excluding any personally identifiable information, to the Attorney General. A single sample copy of a security breach notification shall not be deemed to be within subdivision (f) of Section 6254 of the Government Code.

(g) For purposes of this section, "breach of the security of the system" means unauthorized acquisition of computerized data that compromises the security, confidentiality, or integrity of personal information maintained by the person or business.

Good faith acquisition of personal information by an employee or agent of the person or business for the purposes of the person or business is not a breach of the security of the system, provided that the personal information is not used or subject to further unauthorized disclosure.

(h) For purposes of this section, "personal information" means either of the following:

(1) An individual's first name or first initial and last name in combination with any one or more of the following data elements, when either the name or the data elements are not encrypted:

(A) Social security number.

(B) Driver's license number or California identification card number.

(C) Account number, credit or debit card number, in combination with any required security code, access code, or password that would permit access to an individual's financial account.

(D) Medical information.

(E) Health insurance information.

(F) Information or data collected through the use or operation of an automated license plate recognition system, as defined in Section 1798.90.5.

(2) A user name or email address, in combination with a password or security question and answer that would permit access to an online account.

(i) (1) For purposes of this section, "personal information" does not include publicly available information that is lawfully made available to the general public from federal, state, or local government records.

(2) For purposes of this section, "medical information" means any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional.

(3) For purposes of this section, "health insurance information" means an individual's health insurance policy number or subscriber identification number, any unique identifier used by a

health insurer to identify the individual, or any information in an individual's application and claims history, including any appeals records.

(4) For purposes of this section, "encrypted" means rendered unusable, unreadable, or indecipherable to an unauthorized person through a security technology or methodology generally accepted in the field of information security.

(j) For purposes of this section, "notice" may be provided by one of the following methods:

(1) Written notice.

(2) Electronic notice, if the notice provided is consistent with the provisions regarding electronic records and signatures set forth in Section 7001 of Title 15 of the United States Code.

(3) Substitute notice, if the person or business demonstrates that the cost of providing notice would exceed two hundred fifty thousand dollars ($250,000), or that the affected class of subject persons to be notified exceeds 500,000, or the person or business does not have sufficient contact information. Substitute notice shall consist of all of the following:

(A) Email notice when the person or business has an email address for the subject persons.

(B) Conspicuous posting, for a minimum of 30 days, of the notice on the Internet Web site page of the person or business, if the person or business maintains one. For purposes of this subparagraph, conspicuous posting on the person's or business's Internet Web site means providing a link to the notice on the home page or first significant page after entering the Internet Web site that is in larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks that call attention to the link.

(C) Notification to major statewide media.

(4) In the case of a breach of the security of the system involving personal information defined in paragraph (2) of subdivision (h) for an online account, and no other personal information defined in paragraph (1) of subdivision (h), the person or business may comply with this section by providing the security breach

notification in electronic or other form that directs the person whose personal information has been breached promptly to change his or her password and security question or answer, as applicable, or to take other steps appropriate to protect the online account with the person or business and all other online accounts for which the person whose personal information has been breached uses the same user name or email address and password or security question or answer.

(5) In the case of a breach of the security of the system involving personal information defined in paragraph (2) of subdivision (h) for login credentials of an email account furnished by the person or business, the person or business shall not comply with this section by providing the security breach notification to that email address, but may, instead, comply with this section by providing notice by another method described in this subdivision or by clear and conspicuous notice delivered to the resident online when the resident is connected to the online account from an Internet Protocol address or online location from which the person or business knows the resident customarily accesses the account.

(k) Notwithstanding subdivision (j), a person or business that maintains its own notification procedures as part of an information security policy for the treatment of personal information and is otherwise consistent with the timing requirements of this part, shall be deemed to be in compliance with the notification requirements of this section if the person or business notifies subject persons in accordance with its policies in the event of a breach of security of the system.

Education Code
Title 2, Division 4, Part 27

Chapter 9. Pupil and Personnel Health

Section

Section 49414.7. Emergency stock albuterol inhalers

49414.7. Emergency stock albuterol inhalers

(a) School districts, county offices of education, and charter schools may provide emergency stock albuterol inhalers, including, if necessary, single-use disposable holding chambers, to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use an emergency stock albuterol inhaler to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from respiratory distress.

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

(1) “Albuterol” means a bronchodilator used to open the airways by relaxing the muscles around the bronchial tubes.

(2) “Authorizing physician and surgeon” may include, but is not limited to, a physician and surgeon employed by, or contracting with, a local educational agency, a medical director of the local health department, or a local emergency medical services director.

(3) “Inhaler” means a device used for the delivery of prescribed asthma medication that is inhaled.

(4) “Local educational agency” means a school district, county office of education, or charter school.

(5) “Metered-dose inhaler (MDI)” means a pressurized sprayer that delivers a measured amount of a medication.

(6) “Qualified supervisor of health” may include, but is not limited to, a school nurse.

(7) “Respiratory distress” means the sudden appearance of signs and symptoms of difficulty breathing. Signs and symptoms of respiratory distress may include one or more of the following:

(A) Complaints of a tight chest or chest pain.
(B) Wheezing or noisy breathing.
(C) Persistent coughing.
(D) Difficulty breathing.
(E) Appears to be in distress.
(F) Lips or fingernails turning blue.
(G) Shortness of breath.
(8) “Stock albuterol inhaler” means albuterol medication in the form of a metered-dose inhaler (MDI) that is ordered by a health care provider and is not prescribed for a specific person and also includes, if necessary, a single-use disposable holding chamber.
(9) “Volunteer” or “trained personnel” means an employee who has volunteered to administer stock albuterol inhalers to a person if the person is suffering, or reasonably believed to be suffering, from respiratory distress, has been designated by a school, and has received training pursuant to subdivision (d).
(c) Each private elementary and secondary school in the state may voluntarily determine whether or not to make emergency stock albuterol inhalers and trained personnel available at its school. In making this determination, a school shall evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to stock albuterol inhalers and trained personnel. A private elementary or secondary school choosing to exercise the authority provided under this subdivision shall not receive state funds specifically for purposes of this subdivision.
(d) (1) Each public and private elementary and secondary school in the state may designate one or more volunteers to receive initial and annual refresher training, based on the standards developed pursuant to subdivision (e), regarding the storage and emergency use of a stock albuterol inhaler from the school nurse or other qualified person designated by an authorizing physician and surgeon.
(2) Schools are encouraged and recommended to have a minimum of two trained school employees.
(e)(1) The Superintendent shall establish, and post on the department’s internet website, minimum standards of training

for the administration of stock albuterol inhalers that satisfies the requirements of paragraph (2). Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of stock albuterol inhalers that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering stock albuterol inhalers and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the American Academy of Allergy, Asthma and Immunology, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, the California Society of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and others.

(2) Training established pursuant to this subdivision shall include all of the following:

(A) Techniques for recognizing symptoms of respiratory distress.

(B) Standards and procedures for the storage, restocking, and emergency use of stock albuterol inhalers.

(C) Emergency follow up procedures, including calling the emergency 911 telephone number and contacting, if possible, the pupil's parent or guardian and physician.

(D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.

(E) Written materials covering the information required under this subdivision.

(3) Training established pursuant to this subdivision shall be consistent with the most recent guidelines for medication administration issued by the department.

(4) Training established pursuant to this subdivision shall be provided to a volunteer during the volunteer's regular working hours and at no cost to the volunteer.

(5) A school shall retain for reference the written materials prepared under subparagraph (E) of paragraph (2).

(f) Any local educational agency electing to utilize stock albuterol inhalers for emergency aid shall distribute a notice at least once per school year to all staff that contains the following information:
(1) A description of the volunteer request stating that the request is for volunteers to be trained to administer a stock albuterol inhaler to a person if the person is suffering, or reasonably believed to be suffering, from respiratory distress, as specified in subdivision (b).
(2) A description of the training that the volunteer will receive pursuant to subdivision (d).
(g)(1) A qualified supervisor of health at a local educational agency electing to utilize stock albuterol inhalers for emergency aid shall obtain from an authorizing physician and surgeon a prescription for each school for stock albuterol inhalers. A qualified supervisor of health at a local educational agency shall be responsible for stocking the stock albuterol inhalers and restocking it if it is used.
(2) If a local educational agency does not have a qualified supervisor of health, an administrator at the local educational agency shall carry out the duties specified in paragraph (1).
(3) A prescription pursuant to this subdivision may be filled by local or mail order pharmacies or stock albuterol inhaler manufacturers.
(4) An authorizing physician and surgeon shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.
(h) A school nurse or, if the school does not have a school nurse or the school nurse is not onsite or available, a volunteer may administer a stock albuterol inhaler to a person exhibiting potentially life-threatening symptoms of respiratory distress at school or a school activity when a physician is not immediately available. If the stock albuterol inhaler is used, it shall be restocked as soon as reasonably possible, but no later than two

weeks after it is used. Stock albuterol inhalers shall be restocked before their expiration date.
(i) A volunteer shall initiate emergency medical services or other appropriate medical follow up in accordance with the training materials retained pursuant to paragraph (5) of subdivision (e).
(j) (1) A local educational agency electing to utilize stock albuterol inhalers for emergency aid shall not be liable for any civil damages resulting from any act or omission, other than an act or omission constituting gross negligence or willful and wanton misconduct, in the emergency administration of an albuterol inhaler by any of its school nurses or trained volunteers who have volunteered pursuant to subdivision (d).
(2) An employee who volunteers under this section shall be provided defense and indemnification by the local educational agency for any and all civil liability, in accordance with, but not limited to, that provided in Division 3.6 (commencing with Section 810) of Title 1 of the Government Code. This information shall be reduced to writing, provided to the volunteer, and retained in the volunteer's personnel file.
(k) A state agency, the department, or a public school may accept gifts, grants, and donations from any source for the support of the public school carrying out the provisions of this section, including, but not limited to, the acceptance of stock albuterol inhalers from a manufacturer or wholesaler.

GOVERNMENT CODE

9147.7	Joint Sunset Review Committee
9147.8	Joint Sunset Review Committee Report to Public and Make recommendation to Legislature
11009.5	License Process for Business Displaced or Suffering Economic Hardship due to Declared Emergency

9147.7 Joint Sunset Review Committee

(a) For the purpose of this section, "eligible agency" means any agency, authority, board, bureau, commission, conservancy,

council, department, division, or office of state government, however denominated, excluding an agency that is constitutionally created or an agency related to postsecondary education, for which a date for repeal has been established by statute on or after January 1, 2011.

(b) The Joint Sunset Review Committee is hereby created to identify and eliminate waste, duplication, and inefficiency in government agencies. The purpose of the committee is to conduct a comprehensive analysis over 15 years, and on a periodic basis thereafter, of every eligible agency to determine if the agency is still necessary and cost effective.

(c) Each eligible agency scheduled for repeal shall submit to the committee, on or before December 1 prior to the year it is set to be repealed, a complete agency report covering the entire period since last reviewed, including, but not limited to, the following:

(1) The purpose and necessity of the agency.

(2) A description of the agency budget, priorities, and job descriptions of employees of the agency.

(3) Any programs and projects under the direction of the agency.

(4) Measures of the success or failures of the agency and justifications for the metrics used to evaluate successes and failures.

(5) Any recommendations of the agency for changes or reorganization in order to better fulfill its purpose.

(d) The committee shall take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed. An eligible agency shall be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the eligible agency. No eligible agency shall be extended in perpetuity unless specifically exempted from the provisions of this section. The committee may recommend that the Legislature extend the statutory sunset date for no more than one year to allow the committee more time to evaluate the eligible agency.

(e) The committee shall be comprised of 10 members of the Legislature. The Senate Committee on Rules shall appoint five members of the Senate to the committee, not more than three

of whom shall be members of the same political party. The Speaker of the Assembly shall appoint five members of the Assembly to the committee, not more than three of whom shall be members of the same political party. Members shall be appointed within 15 days after the commencement of the regular session. Each member of the committee who is appointed by the Senate Committee on Rules or the Speaker of the Assembly shall serve during that committee member's term of office or until that committee member no longer is a Member of the Senate or the Assembly, whichever is applicable. A vacancy on the committee shall be filled in the same manner as the original appointment. Three Assembly Members and three Senators who are members of the committee shall constitute a quorum for the conduct of committee business. Members of the committee shall receive no compensation for their work with the committee.

(f) The committee shall meet not later than 30 days after the first day of the regular session to choose a chairperson and to establish the schedule for eligible agency review provided for in the statutes governing the eligible agencies. The chairperson of the committee shall alternate every two years between a Member of the Senate and a Member of the Assembly, and the vice chairperson of the committee shall be a member of the opposite house as the chairperson.

(g) This section shall not be construed to change the existing jurisdiction of the budget or policy committees of the Legislature.

(h) This section shall not apply to the Bureau of Medical Marijuana Regulation.

9148.52. Joint Sunset Review Committee Report to Public and Make Recommendations to Legislature

(a) The Joint Sunset Review Committee established pursuant to Section 9147.7 shall review all eligible agencies.

(b) The committee shall evaluate and make determinations pursuant to Article 7.5 (commencing with Section 9147.7).

(c) Pursuant to an evaluation made as specified in this section, the committee shall make a report which shall be available to the public and the Legislature on whether an agency should be

terminated, or continued, or whether its functions should be revised or consolidated with those of another agency, and include any other recommendations as necessary to improve the effectiveness and efficiency of the agency. If the committee deems it advisable, the report may include proposed legislative proposals that would carry out its recommendations.

11009.5 License Process for Business Displaced or Suffering Economic Hardship due to Declared Emergency

(a) For purposes of this section:

(1) "Displaced" means a condition in which the person or business is unable to return to the address of record or other address associated with the license before experiencing economic hardship.

(2) "Economic hardship" means the inability to pay living or business expenses, unless otherwise defined by a state agency pursuant to subdivision (c).

(3) "Emergency" means an emergency as defined in Section 8558 or a declared federal emergency.

(4) "License" includes, but is not limited to, a certificate, registration, or other required document to engage in business.

(b) Notwithstanding any other law, a state agency that issues any business license may establish a process for a person or business that has been displaced or is experiencing economic hardship as a result of an emergency to submit an application, that the agency may grant, for a reduction or waiver of any fees required by the agency to obtain a license, renew or activate a license, or replace a physical license for display.

(c) A fee or waiver process established pursuant to subdivision (b) shall specify, at a minimum, all of the following:

(1) The methodology used by the agency for determining whether a person, as a result of an emergency, has been displaced or is experiencing economic hardship.

(2) The procedure for applying for a reduction or fee waiver.

(3) That the application shall be made within one year of the date on which the emergency was proclaimed or declared.

CALIFORNIA PUBLIC RESOURCES CODE

DIVISION 12.2 CONSUMER PRODUCTS CONTAINING MERCURY

15025. Definitions: Mercury-Added Novelty; Mercury Fever Thermometer; School
15026. Sale of Mercury Fever Thermometer Prohibited; Exception

PUBLIC RESOURCES CODE

Division 12.2. Consumer Products Containing Mercury

15025. Definitions: Mercury-Added Novelty, Mercury Fever Thermometer, School

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

(a) "Mercury-added novelty" means a mercury-added product intended mainly for personal or household enjoyment or adornment. A "mercury-added novelty" includes, but is not limited to, any item intended for use as a practical joke, figurine, adornment, toy, game, card, ornament, yard statue or figure, candle, jewelry, holiday decoration, and item of apparel, including footwear. "Mercury-added novelty" does not include a product that contains no mercury other than in a mercury-added button cell battery.

(b) "Mercury fever thermometer" means a mercury-added product that is used for measuring body temperature. Mercury fever thermometer does not include a digital thermometer that uses mercury-added button cell batteries.

(c) "School" means any school used for the purpose of the education of more than 12 children in kindergarten or any of grades 1 to 12, inclusive.

15026. Sale of Mercury Fever Thermometer Prohibited; Exception

(a) On and after July 1, 2002, no person, other than a person licensed pursuant to Article 9 (commencing with Section 4140)of Chapter 9 of Division 2 of the Business and Professions Code, may sell at retail, or otherwise supply, a mercury fever thermometer to a consumer or patient in this state. A mercury fever thermometer may be sold at retail, or otherwise supplied to a consumer or patient only upon the prescription of a physician, dentist, veterinarian, or podiatrist. A mercury fever thermometer sold at retail shall be accompanied by clear written instructions concerning careful handling to avoid breakage and proper cleanup should breakage occur.

(b) A violation of subdivision (a) is a violation of the requirements of Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code and the California State Board of Pharmacy shall enforce the requirements of subdivision (a) in accordance with Chapter 9.