2008 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

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Business and Professions Code
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Article 1 - Administration

4000. This chapter constitutes, and may be cited as, the Pharmacy Law.

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

(b) The Governor shall appoint seven competent pharmacists 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.

(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, 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 his or her 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) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

4001.1. 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. The Joint Legislative Sunset Review Committee shall review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage, including, but not limited to, a review of the current California pharmacist licensure examination.

4002. (a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.
(b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Seven members of the board constitute a quorum.

4003. (a) The board 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 him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(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 his or her 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 him or her and pay it to the Department of Consumer Affairs, 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 him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.

4004. 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. (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. 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. (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. (a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.
(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.
(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.
(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no
felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.
(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of

Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.
(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.
(e) Any inspector may serve all processes and notices throughout the state.
(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

4009. The board may not adopt or amend any rule or regulation that thereby would conflict with Section 1186 of the Labor Code.

4010. 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. 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. 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.

Article 2 – Definitions

4015. 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" 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.

4017. "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 Health Services, and investigators of the department's Division of Investigation or peace officers engaged in official investigations.

4018. "Board" means the California State Board of Pharmacy.

4019. 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" means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

4022. "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. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053.
(b) "Designated representative-in-charge" means a designated representative or a pharmacist who is the supervisor or manager of a wholesaler or veterinary food-animal drug retailer.
(c) This section shall become operative on January 1, 2006.

4023. "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. 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. (a) Except as provided in subdivision (b), "dispense" means the furnishing of drugs or devices upon a prescription from a physician, 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, physician assistant, naturopathic doctor pursuant to Section 3640.5, or pharmacist acting within the scope of his or her practice.
(b) "Dispense" also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, podiatrist, or veterinarian, or by a certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant acting within the scope of his or her practice.

4025. "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. "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.

4026. "Furnish" means to supply by any means, by sale or otherwise.

4026.5. "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. (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 paragraph (4) of subdivision (a) of Section 4052, "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 paragraph (5) of subdivision (a) of Section 4052, "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 Health Services 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" 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 Health Services 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. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.
(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 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. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this paragraph shall be construed to restrict or expand the services that a hospital pharmacy may provide.

4030. "Intern pharmacist" means a person issued a license pursuant to Section 4208.

4031. "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" 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. (a) "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.
(b) Notwithstanding subdivision (a), "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.
(c) Notwithstanding subdivision (a), "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.

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.
(b) A pedigree shall include all of the following information:
(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are not required to be recorded on a pedigree:

(1) The provision of samples of dangerous drugs by a manufacturer' s employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, 2010, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2011. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

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

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2009. However, the board may extend the date for compliance with this section and Section 4163 until January 1, 2011, in accordance with Section 4163.5.

4035. "Person" includes firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision.

4036. "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 as authorized by this chapter.

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy 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 Health Services 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. (a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her 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.

4039. "Physicians," "dentists," "optometrists," "pharmacists," "podiatrists," "veterinarians," "veterinary surgeons," "registered nurses," "naturopathic doctors," and "physician's 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. (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, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.
(E) A legible, clear notice of the condition 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 either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 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 (3) of subdivision (b) 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.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs.

4041. "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" 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. (a) "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.
(b) This section shall become operative January 1, 2006.

Article 3 – Scope of Practice and Exemptions

4050. (a) 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.
(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.
(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or 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.

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(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, orally or topically, drugs and biologicals pursuant to a prescriber's order.
(4) Perform procedures or functions in a licensed health care facility as authorized by Section **4052**.1.
(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is 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, as authorized by Section **4052**.2.
(6) 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.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Furnish emergency contraception drug therapy as authorized by Section **4052**.3.

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

(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) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

4052.1. (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. (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, 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 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 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 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.

4052.3. (a) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may 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 section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

4052.4. 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. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, 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. 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.

4052.5. (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.

4052.7. (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.

4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.
(b) An individual 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) He or she shall be a high school graduate or possess a general education development equivalent.
(2) He or she shall have a minimum of one year of paid work experience, 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) He or she 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 may 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. (a) Certificates of exemption issued or renewed pursuant to Section 4053 prior to January 1, 2005, shall remain valid until their expiration date or until January 1, 2007, whichever date is earlier.
(b) Individuals in possession of a current and valid certificate of exemption shall be issued a license as a designated representative if the individual satisfies the requirements of Section 4053 and pays the fee required by subdivision (i) of Section 4400.
(c) This section shall become inoperative and be repealed on January 1, 2007, unless a later enacted statute, that becomes operative on or before December 31, 2006, amends or repeals that date.

4054. Section 4051 shall not apply to a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.

4055. 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. (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. (a) Except as provided in Sections 4006, 4240, and 4342, this chapter does not apply to the retail sale of nonprescription drugs that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.
(b) This chapter does not apply to specific dangerous drugs and dangerous devices listed in board regulations, where the sale or furnishing is made to any of the following:

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

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

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

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

(2) Hypodermic needles and syringes.

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

(d) This chapter does not apply to the storage of devices in secure central or ward supply areas of a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, or pursuant to Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.
(e) This chapter does not apply to the retail sale of vitamins, mineral products, or combinations thereof or to foods, supplements, or nutrients used to fortify the diet of humans or other animals or poultry and labeled as such that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state labeling requirements.
(f) This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of nursing. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of nursing for purposes of this subdivision are those schools recognized as training facilities by the California Board of Registered Nursing.

4058. 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. (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 Health Services. 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 Examining Committee 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. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

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

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

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

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices. (f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

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

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

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

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

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

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

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

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, 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 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 either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

4061. (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, 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, 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. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist 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 shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

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

4063. 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. (a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

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

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

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

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

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

4065. (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. (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. (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 a good faith prior examination of a 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 a good faith prior examination of a 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, "good faith 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. (a) Notwithstanding any provision of this chapter, 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) The prescriber shall be responsible for any error or omission related to the drugs dispensed.

Article 4 – Requirements for Prescriptions

4070. (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. 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. (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) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.
(c) No 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.

4072. (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 Health Services 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. (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.

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.
(b) The board may by regulation require additional information or labeling.
(c) This section shall not apply to drugs furnished to patients in conjunction with treatment or emergency services provided in health facilities or, except as provided in subdivision (d), to drugs furnished to patients pursuant to subdivision (a) of Section 4056.
(d) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge and each medication given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication, 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 provision of law shall be construed to require that only a pharmacist provide this consultation.

4075. 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. (a) A pharmacist shall not dispense any 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 where 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 a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 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 a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
(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 for which the drug was prescribed if requested by the patient and the condition 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 any 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 a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(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 his or her scope of practice.

4076.5. (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) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

4077. (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. (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.

Article 5 – Authority of Inspectors

4080. 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. (a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

(c) The pharmacist-in-charge or 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 or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

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

4082. 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. (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. (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.

4085. (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. (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. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, or designated representative shall notify the executive officer of the board of the change of address or change of name.
(b) This section shall become operative on January 1, 2006.

4101. (a) A pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.
(b) A designated representative-in-charge of a wholesaler or veterinary food drug-animal retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.

4103. 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. (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 to the board, within 30 days of the receipt or development of 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) 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. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices 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 section shall be retained on the licensed premises for a period of three years from the date of making.
(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and 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) This section shall become operative on January 1, 2006.

4106. 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. The board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy. For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

Article 7 – Pharmacies

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has 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 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, when the ownership of a pharmacy is transferred from one person to another, 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 established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. 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.

4111. (a) Except as otherwise provided 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 person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.
(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) 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 authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) ofparagraph (5) of, subdivision (a) of Section 4052.

4112. (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) All nonresident pharmacies shall register with 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) 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.
(h) The registration fee shall be the fee specified in subdivision (a) of Section 4400.
(i) 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.
(j) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

4113. (a) Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.
(b) 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.
(c) Every pharmacy shall notify the board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge.

4114. (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. (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.
(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.
(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
(d) 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.

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.
(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, 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 the Youth Authority or the Department of Corrections, and 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.

(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 his or her 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 his or her 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.

(g) Notwithstanding subdivisions (a) and (b), 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 (f).
(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

4115.5. (a) Notwithstanding any other provision of 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 a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(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 more than 120 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 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.

(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 a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status.

4116. (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. 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. (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.

4119. (a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Health Services set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

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

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

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.
(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.
(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.
(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

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

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.

4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.
(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.
(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

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

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

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.
(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.
(e) Nothing in this section shall be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

4119.2. (a) Notwithstanding any other provision of law, a pharmacy may furnish epinephrine auto-injectors to a school district or county office of education pursuant to Section 49414 of the Education Code if all of the following are met:
(1) The epinephrine auto-injectors are furnished exclusively for use at a school district site or county office of education.
(2) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be furnished.
(b) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by both the school district or county office of education for a period of three years from the date the records were created. The school district or county office of education shall be responsible for monitoring the supply of auto-injectors and assuring the destruction of expired auto-injectors.

4119.5. (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.

4120. (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 who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler 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. (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. (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. 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. (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. (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. (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. (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.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

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

(d) 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.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

Article 7.5 – Injectable Sterile Drug Products

4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following 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.

(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.2. (a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a 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 injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.
(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding injectable 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 injectable 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 the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy 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. 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.

4127.5. The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

4127.6. 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. On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:
(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
(b) An ISO class 5 cleanroom.
(c) A barrier isolator that provides an ISO class 5 environment for compounding.

4127.8. The board may, at its discretion, issue a temporary license to compound injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, 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 five hundred dollars ($500) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. 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.

Article 9 – Hypodermic Needles and Syringes

4140. No person shall possess or have under his or her control any hypodermic needle or syringe except when acquired in accordance with this article.

4141. 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.

4142. Except as otherwise provided by this article, no hypodermic needle or syringe shall be sold at retail except upon the prescription of a physician, dentist, veterinarian, podiatrist, or naturopathic doctor pursuant to Section 3640.7.

4143. 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. 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 or 4146.

4145. (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 one of the following requirements is met:

(1) The person is known to the furnisher and 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.

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005,
and ending December 31, 2010, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered for the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

(b) 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 animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

4147. (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. 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, or 4145.

4149. (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), no license shall be required if the nonresident distributor sells or distributes solely through a person who is licensed as a wholesaler 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. (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. 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. 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. 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. 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. 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. 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 and Manufacturers

4160. (a) A person may not act as a wholesaler 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) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.
(e) 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.
(f) 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 injectable 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.
(g) This section shall become operative on January 1, 2006.

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler 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 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 shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may 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.
(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(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 injectable 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.
() The registration fee shall be the fee specified in subdivision (f) of Section 4400.

4162. (a) (1) An applicant, that is not a government-owned and operated wholesaler, for the issuance or renewal of a wholesaler license 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) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) 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, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), 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.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends those dates.

4162.5. (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) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) 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, 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.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2015, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends those dates.

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When 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) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

4163.1. It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Sections 4034 and 4163 until January 1, 2011, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees 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.

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

4164. (a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales 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. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.
(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.
(e) This section shall become operative on January 1, 2006.

4165. A wholesaler 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. (a) Any wholesaler that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

4167. A wholesaler shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, on the premises licensed by the board.

4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

4169. (a) A person or entity may not do any of the following:
(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.
(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 provision of 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 Health Services.
(e) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

Effective January 1, 2007
4169. (a) A person or entity may not do any of the following:
(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler 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 provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 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 Health Services.
(e) This section shall become operative on January 1, 2007.

Article 12 – Prescriber Dispensing

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:
(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.
(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).
(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.
(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.
(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section

3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

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

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

4170.5. (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. (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. 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. This chapter does not prevent the dispensing of drugs or devices by registered nurses functioning pursuant to Section 2725.1.

4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 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.

4175. (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 Osteopathic Medical Board of California, the Board of Registered Nursing, the Bureau of Naturopathic Medicine, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, naturopathic doctors, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the 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 – Non-Profit or Free Clinics

4180. (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 20 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.

4181. (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 Health Services relating to the drug distribution service to insure 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. (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 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. No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.

4185. 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. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.
(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.
(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

Article 14 – Surgical Clinics

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). 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) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical 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.

(c) No surgical clinic shall operate without a license issued by the board nor shall it 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.

(d) 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.

4191. (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 Health Services and the board relating to drug distribution to insure 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. (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.

(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.

4193. 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. 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. 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 and all other provisions of the law.

Article 15 – Veterinary Food-Animal Drug Retailers

4196. (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) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. 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. Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge

within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.
(e) 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.
(f) This section shall become operative on January 1, 2006.

4197. (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. (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. (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. (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 written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.
(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. (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.
(f) From January 1, 2004, to July 1, 2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2008, regarding the impact on those applicants of the examination limitations imposed by this section.
The report shall include, but not be limited to, the following information:
(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.
(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.
(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.
(g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

4200.2. 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. (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 Examination Resources 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 Examination Resources 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 Legislative Sunset Review Committee 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. An applicant who fails the national examination may not retake the examination for at least 90 days or for a period established by regulations adopted by the board in consultation with the Office of Examination Resources of the department.

4200.5. (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) In order for the holder of a retired license issued pursuant to this section to restore his or her license to active status, he or she shall pass the examination that is required for initial licensure with the board.

4201. (a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, 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.
(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 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.
(c) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where 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, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other provision of 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 provision of law, the wholesale 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 provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.
(i) For licenses referred to in subdivisions (f), (g), and (h), 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.
(j) This section shall become operative on July 1, 2001.

4202. (a) The board may issue a pharmacy technician license to an individual if he or she 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 the Pharmacy Technician Certification 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 may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.
(e) Once 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.

4203. (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.

4204. (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.

4205. (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. (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 Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

4208. (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. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her 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 such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience.

(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 intern experience. 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.

Article 17 – Continuing Education

4231. (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) 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.

4232. (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.

4234. 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. (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. (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.

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
(a) Gross immorality.
(b) Incompetence.
(c) Gross negligence.
(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.
(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances

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

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions **Code** relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(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.

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

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

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

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

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

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

4301.5. (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. The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

4303. (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 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, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

4304. 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. (a) Any person who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.
(b) Any person who has obtained a license to conduct a pharmacy, who willfully fails to notify the board of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy, 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, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.
(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

4305.5. (a) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.
(b) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of the designated representative-in-charge, and who continues to operate the licensee in the absence of the designated representative-in-charge for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.
(c) A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, 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.
(d) This section shall become operative on January 1, 2006.

4306. 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. 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. 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. (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, or partner of any partnership, corporation, 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, or partner 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, or partner 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, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that 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. Whenever a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner 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, or partner 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. (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. 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. (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 includemnotification 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. (a) The board may cancel the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer 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) In the event that the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer is cancelled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, pharmacy, or veterinary food-animal drug retailer 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 wholesaler, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, pharmacy, or veterinary food-animal drug retailer.
(d) In the event that 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 his or her 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 his or her 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. 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. (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.

4315. (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 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.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee 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 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 legal counsel or authorized representative of the licensee 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 letter of admonishment.
(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 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 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 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 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.
(d) The letter of admonishment 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 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.
(f) 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 Article 19 (commencing with Section 4300).

Article 20 – Prohibitions and Offenses

4320. (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. (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. 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. 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. (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 in the state prison, or by imprisonment in the 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 in the state prison, or by imprisonment in the county jail for not more than one year.

4325. (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.

4326. (a) Any person who obtains a hypodermic needle or hypodermic syringe by a false or fraudulent representation or design or by a forged or fictitious name, or contrary to, or in violation of, any of the provisions of this chapter, is guilty of a misdemeanor.
(b) Any person who has obtained a hypodermic needle or hypodermic syringe from any person to whom a permit has been issued as provided in Article 9 (commencing with Section 4140) and who uses, or permits or causes, directly or indirectly, the hypodermic needle or hypodermic syringe to be used for any purpose other than that for which it was obtained is guilty of a misdemeanor and upon conviction thereof shall be punished by a fine not exceeding one thousand dollars ($1,000), or by imprisonment in a county jail not exceeding one year, or both a fine and imprisonment.

4327. 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. 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. Any nonpharmacist who takes charge of or acts as manager 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. (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 nonpharmacist 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. (a) A person who is neither a pharmacist nor a designated representative and 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 has obtained a license to conduct a veterinary food-animal drug retailer and who 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.
(c) A person who has obtained a license to conduct a wholesaler and who 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.
(d) This section shall become operative on January 1, 2006.

4332. 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. (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. Any person who knowingly violates subdivision (b) of Section 4312 is guilty of a misdemeanor.

4336. (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. 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. 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. (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. 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. Notwithstanding any other provision of law, prescription drugs or devices may be advertised if the advertisement conforms with the requirements of Section 651.

4342. (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 4336 and 4321.

4343. 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. 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. (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. (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. (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. The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.

4366. 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. (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. The board shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the pharmacists recovery program.

4372. 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. 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. (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. (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. 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. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). 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 and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600), except as provided in subdivision (j).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars ($100).

(i) The fee for a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(2) For nonresident wholesalers who have 21 or more wholesaler facilities operating nationwide the application fees for the first 20 locations shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars ($225) and may be increased to three hundred dollars ($300).

(3) The annual renewal fee for a nonresident wholesaler's license

issued pursuant to Section 4161 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(l) 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.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) 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.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

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

4401. 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. (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. 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. 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. 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. 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 State 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 for the use of the board and out of it and not otherwise shall be paid all expenses of the board.

4407. All compensation of members and all other expenses of the board shall be paid out of the examination and registration fees and fines.

4409. 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 and Medicare Beneficiaries

4425. (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 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 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 Services shall monitor pharmacy participation with the requirements of subdivision (a).
(d) The State Department of Health 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. The State Department of Health Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

Other Business and Professions Code Sections

125.3. (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 may request the administrative law judge to 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 where the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).
(e) Where 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 licentiate, 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. (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.

148. 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.

650. (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, 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) (1) 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, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) in the following situations:
(A) In the case of a hospital, by the hospital to members of its medical staff.
(B) In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice.
(C) In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.
(2) The exceptions set forth in this subdivision are adopted to conform state law with the provisions of Section 1860D-4(e)(6) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) and are limited to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals (42 U.S.C. Sec. 1395w-101).

(3) The exceptions set forth in this subdivision shall not be operative until the regulations required to be adopted by the Secretary of the United States Department of Health and Human Services, pursuant to Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395W-104) are effective. If the California Health and Human Services Agency determines that regulations are necessary to ensure that implementation of the provisions of paragraph (1) is consistent with the regulations adopted by the Secretary of the United States Department of Health and Human Services, it shall adopt emergency regulations to that effect.

(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) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in the county jail for not more than one year, or by imprisonment in the state prison, 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 in the state prison or by imprisonment in the state prison and a fine of fifty thousand dollars ($50,000).

650.1. (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. (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. For the purposes of this section, the statement of a practitioner licensed under Chapter 4 (commencing with Section 1600) who limits his or her practice to a specific field or fields shall only include a statement that he or she is certified or is eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board. 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 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. 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.

733. (a) No licentiate shall 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 his or her licensing agency.

(b) Notwithstanding any other provision of 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 his or her employer, in writing, of the drug or class of drugs to which he or she 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) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section 4052.

(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.

17500. 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.

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California Code of Regulations
Title 16, Division 17
Board of Pharmacy

Article 1 – General Provisions

§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 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. Change of Address.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 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: Sections 4005, Business and Professions Code.

§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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 15376, Government Code.

§1706.2. Abandonment of Application Files.

(a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes 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 a pharmacy technician license or a designated representative license 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) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility 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 a 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 4022.2, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, 4205, and 4208 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: Sections 4005, 4120, 4161, 4162, 4304 and 4400, Business and Professions Code.

Article 2. Pharmacies

§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 shall be granted to any entity licensed by the board for off-site storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.

(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 non controlled 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, of the Business and Professions Code. Reference: Sections 4005, 4121 and 4122, of the Business and Professions Code.

§1707.2 Notice to Consumers and Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
(1) upon request; or
(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.
(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) 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.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:
of his or her right to request consultation; and
a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) 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.

(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:

“NOTICE TO CONSUMERS”
At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:
What is the name of the medicine and what does it do?
How and when do I take it – and for how long? What if I miss a dose?
What are the possible side effects and what should I do if they occur?
Will the new medicine work safely with other medicines and herbal supplements I am taking?
What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

(g) In addition to the “NOTICE TO CONSUMERS” referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:
1. The medicine or device is not in stock in the pharmacy,
2. The pharmacist, based upon his or her professional judgment determines providing the item:
is against the law,
could cause a harmful drug interaction, or
could have a harmful effect on your health

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

Authority cited: Sections 4005 and 4122 Business and Professions Code. Reference: Sections 733, 4005 and 4122 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, of the Business and Professions Code. Reference: Sections 4005, 4074, 4121 and 4122, of the 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 and Professions Code. Reference: Sections 4063, 4076, 4081 and 4333, 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, 4332 and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

§1708.3. Radioactive Drugs.

A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.

§1708.4. Pharmacist Handling Radioactive Drugs.

A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.

§1708.5. Pharmacy Furnishing Radioactive Drugs.

A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed.

A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.

A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.

§1709. Names of Owners and Pharmacist in Charge.

(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application 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.

(b) 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 8did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.
(c) The following shall constitute a transfer of permit and require application for a change of ownership: 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.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4058, 4101, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4304, 4305 and 4330, Business and Professions Code.

§1709.1. Designation of Pharmacist in Charge.

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(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 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 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 which 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.
(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: Section 4125, 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.

(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 delivery device to deliver previously dispensed prescription medications provided:
(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.
(3) The device has a means to identify each patient and only release that patient's prescription medications.
(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
(6) The device is located adjacent to the secure pharmacy area.
(7) The device is secure from access and removal by unauthorized individuals.
(8) The pharmacy is responsible for the prescription medications stored in the device.
(9) Any incident involving the device 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.
(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).
(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:
(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.
(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device 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 automated delivery device.
(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.
(5) Orienting participating patients on use of the automated delivery device**,** notifying patients when expected prescription medications are not available in the device**,** and ensuring that patient use of the device does not interfere with delivery of prescription medications.
(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.
(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.
(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 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.

§1714.5. 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.
(c) The components of this assessment shall be on Form 17M-13 (Rev 10/07) entitled “Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment (or Form 17M-14 (Rev 10/07) entitled “Hospital Pharmacy Self-Assessment” which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4305, 4330, 4332 and 4333, Business and Professions Code.

§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.

Authority cited: Sections 4005, Business and Professions Code. Reference: Sections 11164 and 11165, Health and Safety Code.

§1715.6. Reporting Drug Loss.

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions 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.

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:
(a) “Reasonable quantity” means that quantity of an unapproved drug which:
(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and

(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.

(b) “Compounded medication” means medications actually compounded by the pharmacy supplying them to a prescriber.

(c) “Prescriber office use” means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

§1716.2. Record Requirements--Compounding for Future Furnishing.

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

(1) The date of preparation.

(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.

(6) The name(s) of the manufacturer(s) of the raw materials.

(7) The quantity in units of finished products or grams of raw materials.

(8) The package size and the number of units prepared.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, 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.

Note: 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.

§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 twelve months from the date of the incident, and shall surrender his or her intern card 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: Section 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.

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. Intern Pharmacist.

(a) An intern pharmacist is a person who holds a valid intern card.
(b) An intern card shall be issued for a period of:
(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.
(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.
(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.
(4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.
(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:
(1) Persons who have not completed experience requirements.
(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.
(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.
(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.

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.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005, 4030, 4100 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.

(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 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 Pharmacy Foundation of California.

(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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 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 requests 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 in the prior 24 months.
(b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, 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.

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) The following classes of drugs may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol:

(1) Muscle relaxants.

(2) Analgesics with central nervous system depressant effects.

(3) Antipsychotic drugs including phenothiazines.

(4) Antidepressants.

(5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(6) All Schedule II, III, IV and V depressant or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.

(7) Anticholinergic agents and other drugs which may impair vision.

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle.

(1) Disulfiram and other drugs (e.g. chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

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

(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 (a)(8)~~(ii)~~ 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 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.

(2) Purpose: To provide access to emergency contraceptive medication within required limits 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 state 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) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

(4) The pharmacist shall provide the 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 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 4052b(3).

(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 compatible with product information 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. 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 profile 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) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception

Dedicated Emergency Contraception				
Brand	Manufacturer	Tablets per Dose	EthinylEstradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Duramed	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Duramed	1 tablet per dose	0	0.75
Preven	Duramed	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hoursapart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50

Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
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 ECP dose; repeat as needed every 4-6 hours
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: Section 4052 and 4052.3, Business and Professions Code.

Article 6. Fees

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:
(a) The fee for the issuance of a pharmacy license is four hundred dollars ($400). The fee for the annual renewal of pharmacy license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).
(b) The fee for the issuance of a temporary license is two hundred fifty dollars ($250).
(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25).
(d) The fee for application and examination as a pharmacist is one hundred eighty-five dollars ($185).
(e) The fee for regrading an examination is eighty-five dollars ($85).
(f) The fee for the issuance of an original pharmacist license is one hundred fifty dollars ($150).
(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars ($150). The penalty fee for failure to renew is seventy-five dollars ($75).
(h) The fee for the issuance or renewal of a wholesaler's license is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is one hundred twenty five dollars ($125). The penalty for failure to renew is sixty-two dollars and fifty cents ($62.50).
(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars ($110) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars ($150) The penalty for failure to renew is seventy-five dollars ($75).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(l) The fee for an intern pharmacist license is seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state is twenty dollars ($20).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is four hundred dollars ($400). The fee for the annual renewal of a clinic license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).
(r) The fee for a veterinary food-animal drug retailer license is four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer is two hundred and fifty dollars ($250). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250)
(s) The fee for the issuance of a retired pharmacist license shall be thirty dollars ($30).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4127.5, 4196, 4200, 4400, 4401 and 4403, Business and Professions Code.

§1750. Fee Schedule--Health and Safety Code.

The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars ($100). The penalty for failure to renew is twenty-five dollars ($25).

Authority cited: Section 4005, Business and Professions Code; and Section 11127, Health and Safety Code. Reference: Section 11127, Health and Safety Code.

Article 7. Sterile Injectable Compounding

§1751. Sterile Injectable Compounding Area. for Parenteral Solutions.

(a) The pharmacy shall have a designated area for the preparation of sterile injectable products shall meet the following standards:

(1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
(2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.31 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
(3) Be ventilated in a manner in accordance with Section 505.12 Title 24, Part 4, Chapter 5 of the California Code of Regulations.
(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
(5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
(6) A sink shall be included in accordance in Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations.
(7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

§1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

(a) No sterile injectable product shall be prepared if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected. 2
(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

§1751.02. Policies and Procedures.

(a) Written policies and procedures associated with the pharmacy's preparation and dispensing
of sterile injectable products shall include, but not be limited to:
(1) Compounding, filling, and labeling of sterile injectable compounds.
(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
(3) Equipment and supplies.
(4) Training of staff in the preparation of sterile injectable products.
(5) Procedures for handling cytotoxic agents.
(6) Quality assurance program.
(7) Record keeping requirements.
(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
(c) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
(2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
(3) Policies and procedures must address at least the following:
(A) Competency evaluation.
(B) Storage and handling of products and supplies.
(C) Storage and delivery of final products.
(D) Process validation.
(E) Personnel access and movement of materials into and near the controlled area.
(F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area. 3
(I) For sterile batch compounding, written policies and procedures must be established for the use of master

formulas and work sheets and for appropriate documentation.
(J) Sterilization.
(K) End-product evaluation and testing.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.1. Laminar Flow Biological Safety Cabinet

Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code

§1751.2. Labeling Requirements.

In addition to existing labeling requirements, a pharmacy which compounds sterile products shall include the following information on the labels for those products:
(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
(b) Name and concentrations of ingredients contained in the sterile injectable product.
(c) Instructions for storage and handling.
(d) All cytotoxic agents shall bear a special label which states “Chemotherapy-Dispose of Properly.”

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.3. Recordkeeping Requirements.

(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 shall, in addition to those records required by section 1716.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
(1) The training and competency evaluation of employees in sterile product procedures.
(2) Refrigerator and freezer temperatures.
(3) Certification of the sterile compounding environment.
(4) Other facility quality control logs specific to the pharmacy’s policies and procedures (e.g., cleaning logs for facilities and equipment).
(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.4. Attire.

(a) When preparing cytotoxic agents, gowns and gloves shall be worn.
(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
(1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
(2) Cleanroom garb must be donned and removed outside the designated area.
(3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
(4) Head and facial hair must be kept out of the critical area or be covered.
(5) Gloves made of low-shedding materials are required.
(c) The requirements of this subdivision do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.5. Training of Staff, Patient, and Caregiver.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile Injectable products,parenteral solutions including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
(A) Aseptic technique.
(B) Pharmaceutical calculations and terminology.
(C) Sterile product compounding documentation.
(D) Quality assurance procedures.
(E) Aseptic preparation procedures.
(F) Proper gowning and gloving technique.
(G) General conduct in the controlled area.
(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
(I) Sterilization techniques.
(J) Container, equipment, and closure system selection.
(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person’s proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.6. Disposal of Waste Material.

Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and

shall be in conformance with local health jurisdiction.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.7. Quality Assurance and Process Validation.

(a) There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectablel products.

(b) Each individual involved in the preparation of sterile injectable products must successfully complete a validation process on technique before being allowed to prepare sterile Injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.9. Reference Materials.

There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1751.10. 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.

§1751.11. 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 1:1000;
(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 policy 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.

§1751.12. 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 1751.11.
(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 1751.11.

Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

REFERENCED TITLE 24 REGULATIONS

Sec. 490A.3
Compounding Area for Parenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room.
2. Have non-porous and cleanable surfaces, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solution. There shall be sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials.
4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.

Sec. 505.12
Pharmacies: Compounding Area forParenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. Be ventilated in a manner not interfering with laminar air flow.

Sec. 505.12.1
Pharmacies: Laminar Flow Biological Safety Cabinet. In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.

Article 8. Prohibitions and Discipline

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled “Disciplinary Guidelines” (Rev. 1/2001), 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: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, 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.

§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.

(a) 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) 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.

(b) 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.

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.

(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.

§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 10. Wholesalers

§1780. Minimum Standards for Wholesalers.

The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:
(a) A wholesaler shall store dangerous drugs in a secured and lockable area.
(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale 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 United States Pharmacopeia Standards (1990, 22nd Revision).
(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 wholesaler premises shall be well-lighted.
(d) All materials must be examined upon receipt or 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 appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
(f) Policies and procedures must be written and made available upon request by the board.
(1) Wholesale drug distributors 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) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
(4) Each wholesaler 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 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 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

§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.

NOTE: 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. Exemption Certificate.

A registered pharmacist, or an designated representative certified in accordance with Section 4053 or 4054 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.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053 or 4054, Business and Professions Code.

§1782. Reporting Sales of Drugs Subject to Abuse.

All manufacturers and wholesalers 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; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

§1783. Manufacturer or Wholesaler Furnishing Drugs and Devices.

(a) A manufacturer or wholesaler 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 or wholesaler 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 or wholesaler 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 or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler 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 or wholesaler by the next business day after the delivery to the pharmacy receiving area.
(d) A manufacturer or wholesaler 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 or wholesaler 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 or wholesaler 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 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler'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 designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new wholesaler permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler to a new address.
(c) The components of this assessment shall be on Form 17M-26 (rev. ~~8~~12/14/2006) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 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 application for a pharmacy technician license (Form 17A-5 (Rev. 9/94)) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for registration as a pharmacy technician 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). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.
(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, 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 Section 1749, subdivision (c).

Authority cited: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions 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) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
(1) Knowledge and understanding of different pharmacy practice settings.
(2) 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.
(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

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.

§1793.7. 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.

Note: Authority cited: Section 4005 and 4115, Business and Professions Code. Reference: Section 4005, 4052.1 and 4115 Business and Professions Code.

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Chapter 2 Health Facilities

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Division 2

Chapter 2 - Health Facilities

1261.6. (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 4119.1 of the Business and Professions **Code**, the automated drug delivery system shall be subject to all of the following requirements:

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

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

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

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

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

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

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

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

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

(C) This paragraph shall remain in effect only until January 1, 2012, unless a later enacted statute is enacted on or before January 1, 2012, deletes or extends that date.

(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, or similar technology, 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, or drawers 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, or drawers 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 pockets, cards, or drawers 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.

California Uniform Controlled Substance Act
Health and Safety Code 11000 et seq.
Division 10

Chapter 1 – General Provisions and Definitions

11000. This division shall be known as the "California Uniform Controlled Substances Act."

11001. Unless the context otherwise requires, the definitions in this chapter govern the construction of this division.

11002. "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" 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" means the Attorney General of the State of California.

11005. "Board of Pharmacy" means the California State Board of Pharmacy.

11006.5. "Concentrated cannabis" means the separated resin, whether crude or purified, obtained from marijuana.

11007. "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" 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.

11009. "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

11010. "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" means a practitioner who dispenses.

11012. "Distribute" means to deliver other than by administering or dispensing a controlled substance.

11013. "Distributor" means a person who distributes. The term distributor also includes warehousemen handling or storing controlled substances and customs brokers.

11014. "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. (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" means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

11016. "Furnish" has the same meaning as provided in Section 4048.5 of the Business and Professions Code.

11017. "Manufacturer" has the same meaning as provided in Section 4034 of the Business and Professions Code.

11018. "Marijuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

11019. "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" 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" means the plant of the species Papaver somniferum L., except its seeds.

11022. "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" has the same meaning as provided in Section 4035 of the Business and Professions Code.

11024. "Physician," "dentist," "podiatrist," "pharmacist," "veterinarian," and "optometrist" means persons who are licensed to practice their respective professions in this state.

11025. "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

11026. "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. (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" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

11029.5. "Security printer" means a person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

11030. "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" has the same meaning as provided in Section 4038 of the Business and Professions Code.

11032. 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. As used in this division, except as otherwise defined, the term "isomer" includes optical and geometrical (diastereomeric) isomers.

Chapter 2 – Standards and Schedules

11053. 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. (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-alpha-methylphenethylamine; 4-bromo-2,5-DMA.
(2) 2,5-dimethoxyamphetamine--Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.
(3) 4-methoxyamphetamine--Some trade or other names: 4-methoxy-alpha-methylphenethylamine, paramethoxyamphetamine, PMA.
(4) 5-methoxy-3,4-methylenedioxy-amphetamine.
(5) 4-methyl-2,5-dimethoxy-amphetamine--Some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP."
(6) 3,4-methylenedioxy amphetamine.
(7) 3,4,5-trimethoxy amphetamine.
(8) Bufotenine--Some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-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-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; Tabernantheiboga.
(12) Lysergic acid diethylamide.
(13) Marijuana.
(14) Mescaline.
(15) Peyote--Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts (interprets 21 U.S.C. Sec. 812(c), Schedule 1(c)(12)).
(16) N-ethyl-3-piperidyl benzilate.
(17) N-methyl-3-piperidyl benzilate.

(18) Psilocybin.
(19) Psilocyn.
(20) Tetrahydrocannabinols. Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following: delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; delta 3,4 cis or trans tetrahydrocannabinol, and its optical isomers. (Since 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. (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) Apomorphine.
(H) Codeine.
(I) Ethylmorphine.
(J) Hydrocodone.
(K) Hydromorphone.
(L) Metopon.
(M) Morphine.
(N) Oxycodone.
(O) Oxymorphone.
(P) 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.

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

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

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

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

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

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

(A) Amobarbital

(B) Secobarbital

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

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

(A) Amobarbital

(B) Secobarbital

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

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

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

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

(d) Nalorphine.

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

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

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

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

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

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

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

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

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

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

(1) Androisoxazole.
(2) Androstenediol.
(3) Bolandiol.
(4) Bolasterone.
(5) Boldenone.
(6) Chlormethandienone.
(7) Clostebol.
(8) Dihydromesterone.
(9) Ethylestrenol.
(10) Fluoxymesterone.
(11) Formyldienolone.
(12) 4-Hydroxy-19-nortestosterone.
(13) Mesterolone.
(14) Methandriol.
(15) Methandrostenolone.
(16) Methenolone.
(17) 17-Methyltestosterone.
(18) Methyltrienolone.
(19) Nandrolone.
(20) Norbolethone.
(21) Norethandrolone.
(22) Normethandrolone.
(23) Oxandrolone.
(24) Oxymestrone.
(25) Oxymetholone.
(26) Quinbolone.
(27) Stanolone.
(28) Stanozolol.
(29) Stenbolone.
(30) Testosterone.
(31) Trenbolone.
(32) Chorionic Gonadotropin (HGC).

(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. (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 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).

(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. (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.

Chapter 3 – Regulation and Control

Article 1 – Reporting

11100. (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) Thionylchloride.
(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 (A) 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 (B) 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 California Department of Health Services; registration number issued by the Federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the California 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 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 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. (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. (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. 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. The Department of Justice may adopt all regulations necessary to carry out the provisions of this part.

11103. 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. (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. 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. (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. (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. (a) The Bureau of Narcotic Enforcement, 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 bureau, 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 bureau 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 bureau 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 bureau, 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 bureau shall determine whether the order shall remain in effect, be dissolved, or be modified.
(f) The bureau 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 bureau abused its discretion in the issuance of the interim order. Abuse of discretion is established if the respondent bureau 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 bureau 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 bureau 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 bureau on matters of law. The bureau 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 bureau 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 bureau. 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) 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 bureau.
If the interim order issued by the bureau 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 bureau 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 bureau 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. (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. (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 Health Services; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of 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. (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 Health Services; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of 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.

Chapter 4 - Prescriptions

Article 1 – Requirements of Prescriptions

11150. No person other than a physician, dentist, podiatrist, or veterinarian, 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 either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 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, 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.

11150.6. 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. 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. No person shall write, issue, fill, compound, or dispense a prescription that does not conform to this division.

11153. (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. (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. (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. 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. (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 person shall issue a prescription that is false or fictitious in any respect.

11158. (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 directly to an ultimate user a controlled substance classified in Schedule II 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. Practitioners dispensing drugs pursuant to this subdivision shall meet the requirements of subdivision (f) of Section 11164.
(c) Except as otherwise prohibited or limited by law, a practitioner specified in Section 11150, may administer controlled substances in the regular practice of his or her profession.

11159. 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. 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. (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.

11161. (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 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. (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; and all managing general partners, if any.
(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, or managing general partner.
(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have 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 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 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 pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits 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.
(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.
(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) (1) The department may 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.

11161.7. (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. (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 and
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 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.

(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 subdivision (a) of Section 1206 that has 25 or more physicians or surgeons preprinted on the form.

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

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

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

(d) This section shall become operative on July 1, 2004.

11162.5. (a) Every person who counterfeits a prescription blank purporting to be an official prescription blank prepared and issued pursuant to Section 11161, or knowingly possesses more than three such counterfeited prescription blanks, shall be punished by imprisonment in the state prison or by imprisonment in the 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, shall be guilty of a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding one thousand dollars ($1,000), or by both.

11162.6. (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. 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. (a) (1) Notwithstanding any other provision of 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) All prescriptions for Schedule II and Schedule III controlled substances 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) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers 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, 2005.

11164.5. (a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.

(b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a

controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.
(c) 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.
(d) 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. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) 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 persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) 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 ultimate user.

(2) 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.

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

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

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis **code**), if available.

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

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

(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice 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.

(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered 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.

11165.5. (a) The Board of Pharmacy shall, contingent upon the availability of adequate funds, evaluate the viability of the implementing real time reporting and access to data on prescriptions for controlled substances in the operation of the Controlled Substances Utilization Review and Evaluation System (CURES). For the purposes of this subdivision, "real time reporting" means the ability to send and access prescription data instantaneously in the operation of CURES.
(b) The Board of Pharmacy, in consultation with the Medical Board of California and Department of Justice, shall contract with a vendor to prepare a feasibility study report in accordance with the State Administrative Manual (SAM) to analyze the costs, benefits, and processes necessary to implement real time reporting of controlled substances in the operation of CURES.
(c) This section shall be implemented to the extent that sufficient nonstate funds are received to cover the costs to the Board of Pharmacy of providing staff, and for the preparation of the report. The costs incurred by the Board of Pharmacy implementing this section shall be solicited and funded from nongovernmental entities. It is not the responsibility of the Board of Pharmacy to solicit the funds for this study. The costs for the feasibility study report and the staff to support the preparation of the report shall be no more than two hundred fifty thousand dollars ($250,000). Any nonstate funds donated for that purpose are appropriated to the Board of Pharmacy for that purpose.
(d) The board shall submit the feasibility study report to the Legislature on or before July 1, 2007, or within 18 months of receipt of sufficient funding, whichever date is later.
(e) This section shall remain in effect until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2008, deletes or extends that date.

11166. 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. 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. (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 July 1, 2004.

11168. (a) The prescription book containing the prescriber's copies of prescriptions issued shall be retained by the prescriber which shall be preserved for three years.
(b) This section shall remain in effect only until January 1, 2008, and as of that date is repealed.

11170. No person shall prescribe, administer, or furnish a controlled substance for himself.

11171. No person shall prescribe, administer, or furnish a controlled substance except under the conditions and in the manner provided by this division.

11172. No person shall antedate or postdate a prescription.

11173. (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. No person shall, in connection with the prescribing, furnishing, administering, or dispensing of a controlled substance, give a false name or false address.

11175. 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. A person who fills a prescription shall keep it on file for at least three years from the date of filling it.

11180. 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. (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.

(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. The record shall be preserved for three years. Every person who violates any provision of this section is guilty of a misdemeanor.

11192. 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. 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. (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. 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 – Pharmacist's Records

11205. 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. 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. (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. 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. (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. A physician, surgeon, dentist, veterinarian, 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 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 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, 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 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 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 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 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 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. 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. 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. 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 such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and 11481. Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Article 2 – Treatment of Addicts for Addiction

11215. (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. 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 Mental Health, 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 Mental Health 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 Alcohol and Drug Programs 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 Alcohol and Drug Programs pursuant to Article 3 (commencing with Section 11875) of Chapter 1 of Part 3 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. 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. 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. 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. At the end of 30 days from the first treatment, the prescribing or furnishing of controlled substances, except methadone or LAAM, shall be discontinued.

11222. 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. No veterinarian shall prescribe, administer, or furnish a controlled substance for himself or any other human being.

11241. 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. (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. 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. 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. The written orders or blank forms shall be preserved for at least three years after the date of the last entry made.

11255. 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. 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. (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 which 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) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within in the city, for the period commencing January 1, 2005, and ending December 31, 2010, subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

Health & Safety Code 150200.
Division 116.

Chapter 1 - Surplus Medication Collection And Distribution

150200. 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.

150201. For purposes of this division, "medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

150202. Notwithstanding any other provision of law, a licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease, may donate unused medications under a program established pursuant to this division.

150203. 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. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish 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 county-owned or county-contracted, licensed pharmacy.

(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 skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.

(d) 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.

(e) A pharmacist 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 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 any of the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) 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.

(j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) The pharmacy shall keep complete records of the acquisition and disposition of medication donated to and dispensed under the repository and distribution program. These records shall be kept separate from the pharmacy'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 act 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 and

Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with USP standards and the Pharmacy Law.
(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy 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.

150205. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:
(a) A prescription drug manufacturer, wholesaler, governmental entity, county-owned or county-contracted licensed pharmacy, or skilled nursing facility.
(b) A pharmacist or health care professional who accepts or dispenses prescription drugs.

150206. The immunities provided in Section 150205 shall not apply in cases of noncompliance with this division, bad faith, or gross negligence.

150207. Nothing in this division shall affect disciplinary actions taken by licensing and regulatory agencies.

California Civil Code

Division 1. Persons
Part 2.6. Confidentiality of Medical Information

Chapter 1. Definitions

Chapter 2. Disclosure of Medical Information by Providers

Chapter 6. Relationship to Existing Law

Chapter 7. Violations

Confidentiality of Medical Information Act
Civil Code Section 56 et seq.
Division 1, Part 2.6

Chapter 1 - Definitions

56. This part may be cited as the Confidentiality of Medical Information Act.

56.05. 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) "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).
(d) "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).
(e) "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.
(f) "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.

(g) "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 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.
(h) "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.

(i) "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.
(j) "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.

56.06. (a) Any corporation organized for the primary purpose of maintaining medical information in order to make the information available to the patient or to a provider of health care at the request of the patient or a provider of health care, for purposes of diagnosis or treatment of the patient, 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 corporation 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 corporation described in subdivision (a) shall maintain the same standards of confidentiality required of a provider of health care with respect to medical information disclosed to the corporation.
(c) Any corporation described in subdivision (a) shall be subject to the penalties for improper use and disclosure of medical information prescribed in this part.

56.07. (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. (a) No provider of health care, health care service plan, or contractor shall 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) By a court pursuant to an order of that court.

(2) By a board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.

(3) By 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) By 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) By 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 any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

(6) By a search warrant lawfully issued to a governmental law enforcement agency.

(7) By 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) By a coroner, when requested in the course of an investigation by the 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 when otherwise authorized by the decedent's representative. Medical information requested by the coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation and shall be disclosed to the coroner without delay upon request.

(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 any 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 any 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, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of 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 any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the provider of health care or 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 any way that would violate this part.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b).

(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 any way that would disclose the identity of any patient or be violative of 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 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 may not otherwise be disclosed by a health care service plan except in accordance with the provisions of this part.

(11) Nothing in this part shall 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 Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court investigator engaged in determining the need for an initial conservatorship or continuation of an existent conservatorship, if the patient is unable to give informed consent, 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 existent 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, the terms "tissue bank" and "tissue" have the same meaning 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, such as the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

(15) Basic information, including the patient's name, city of residence, age, sex, and general condition, may be disclosed to a state 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 any way that would be violative of 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 any 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, provided that the disease management services and care are authorized by a treating physician, or (B) to any 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, provided that 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. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of any 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 such as 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.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor or corporation and its subsidiaries and affiliates shall 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 any 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.

56.101. Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records 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 records shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.

56.102. (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. (a) Notwithstanding subdivision (c) of Section 56.10, no provider of health care, health care service plan, or contractor may release medical information to persons or entities 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 subdivision (d) of Section 56.05 of the Civil Code.

(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) 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. 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 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 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.

56.11. 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, 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. 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. 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. 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. 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 canceling 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. Unless there is a specific written request by the patient to the contrary, nothing in this part shall be construed to prevent a provider, 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 subdivision (c) of Section 56.05.

Chapter 6. Relationship to Existing Law

56.30. 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 11977 of the Health and Safety Code dealing with narcotic 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.

Chapter 7. Violations

56.35. 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. (a) Any 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, any individual may bring an action against any 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) Nominal damages of one thousand dollars ($1,000). In order to recover under this paragraph, it shall not be 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, any 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) Any 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) Any 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, or 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. Nothing in this subdivision shall 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.

(3) (A) Any 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) Any 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, or 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. Nothing in this subdivision shall 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) Nothing in this subdivision shall be construed as authorizing an administrative fine or civil penalty under both paragraphs (2) and (3) for the same violation.

(5) Any 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 licensing agency or certifying board or court shall consider any one or more 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) 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) Any district attorney.

(C) Any county counsel authorized by agreement with the district attorney in actions involving violation of a county ordinance.
(D) Any city attorney of a city.
(E) Any 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 any city having a full-time city prosecutor or, with the consent of the district attorney, by a city attorney in any city and county.

(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) Nothing in this section shall 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 any other sanctions or remedies authorized by law.

(f) For purposes of this section, "knowing" and "willful" shall have the same meanings as in Section 7 of the Penal Code.

(g) No person who discloses protected medical information in accordance with the provisions of this part shall be subject to the penalty provisions of this part.

56.37. (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.

Public Resources Code
Division 12.2, Chapter 5
Consumer Products Containing Mercury

15025. 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. (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.

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Code section references are as follows: Business and Professions Code sections 125.3, 650-652.5, 4000-4407, 17500; Health and Safety Code sections 11000-11256; Chap. 17, Title 16, California Code of Regulations, sections 1700-1793.7, California Civil Code sections 56 et seq, and the Public Resources Code sections 15025 and 15026.

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