Effective: [See Text Amendments]

West's Annotated California Codes Currentness
Business and Professions Code (Refs & Annos)
Division 2. Healing Arts (Refs & Annos)
➡ Chapter 9. Pharmacy (Refs & Annos)
Article 1. Administration (Refs & Annos)

§ 4000. Short title

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

Effective: January 01, 2013

§ 4001. Board of Pharmacy; administration and enforcement of chapter; membership; terms of office; vacancies; compensation

(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) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

Effective: January 01, 2003

§ 4001.1. Priority to protect the public

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.

Effective: April 13, 2004

§ 4001.5. Review of state's shortage of pharmacists; recommendations on course of action

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

Effective: January 01, 2004

§ 4002. Officers; principal office; meetings; quorum

(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.

Effective: January 01, 2013

§ 4003. Executive officer; appointment; compensation; duties

(a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in 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, 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) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.

Effective: [See Text Amendments]

§ 4004. Teaching; conditions for board members

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

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

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

Effective: [See Text Amendments]

§ 4004.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2006

§ 4005. Rules and regulations for protection of public

(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.

Effective: [See Text Amendments]

§ 4006. Regulations; dangerous drugs

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.

Effective: [See Text Amendments]

§ 4007. Rules and regulations; limitations

(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.

Effective: January 01, 2005

§ 4008. Inspectors; powers and duties; arrests; civil liability; service of notice and process

(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.

Effective: [See Text Amendments]

§§ 4008.1 to 4008.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4008.1 to 4008.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4008.1 to 4008.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4008.1 to 4008.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4008.1 to 4008.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§ 4009. Rules or regulations conflicting with Labor Code § 1186

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

Effective: [See Text Amendments]

§ 4010. Law officers; immunity

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.

Effective: [See Text Amendments]

§ 4010.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4011. Administration and enforcement of chapter; Uniform Controlled Substances Act

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10

(commencing with Section 11000) of the Health and Safety Code).

Effective: [See Text Amendments]

§ 4012. Copies; laws and regulations relating to dangerous drugs

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.

Effective: January 01, 2011

§ 4013. E-mail notification list; owners of two or more licensed facilities

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

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

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

(d) This section shall become operative on July 1, 2010.

Effective: [See Text Amendments]

§ 4014. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

Article 2. Definitions (Refs & Annos)

§ 4015. Construction of chapter

For purposes of this chapter, the definitions of the terms in this article shall govern the construction of this chapter, unless otherwise indicated.

Effective: [See Text Amendments]

§ 4016. Administer defined

"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.

Effective: January 01, 2014

§ 4016.5. Advanced practice pharmacist defined

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

Effective: January 01, 2011

§ 4017. Authorized officers of the law defined

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

Effective: [See Text Amendments]

§ 4018. Board defined

"Board" means the California State Board of Pharmacy.

Effective: January 01, 2001

§ 4019. Order defined

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.

Effective: [See Text Amendments]

§ 4020. Repealed by Stats.1997, c. 549 (S.B.1349), § 13

Effective: [See Text Amendments]

§ 4021. Controlled substance defined

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

Effective: January 01, 2014

§ 4021.5. "Correctional pharmacy" defined

"Correctional pharmacy" means a pharmacy, licensed by the board, located within a state correctional facility for the purpose of providing pharmaceutical care to inmates of the state correctional facility.

Effective: January 01, 2004

§ 4022. Dangerous drug or dangerous device defined

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

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

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

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

Effective: January 01, 2010

§ 4022.5. Designated representative or designated representative-in-charge defined

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

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

Effective: [See Text Amendments]

§ 4023. Device defined

"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.

Effective: January 01, 2006

§ 4023.5. Direct supervision and control

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

Effective: October 04, 2005

§ 4024. Dispense defined

(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.

Effective: [See Text Amendments]

§ 4025. Drug defined

"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).

Effective: [See Text Amendments]

§ 4025.1. Nonprescription drug defined

"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.

Effective: [See Text Amendments]

§ 4026. Furnish defined

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

Effective: January 01, 2005

§ 4026.5. Good standing defined

"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.

Effective: January 01, 2010

§ 4027. Skilled nursing facility; intermediate care facility; health care facilities; licensed home health agency; licensed clinic; definitions

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

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

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

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

Effective: January 01, 2011

§ 4028. Licensed hospital defined

"Licensed hospital" means an institution, place, building, or agency that maintains and operates organized facilities for one or more persons for the diagnosis, care, and treatment of human illnesses to which persons may

be admitted for overnight stay, and includes any institution classified under regulations issued by the State Department of Public Health as a general or specialized hospital, as a maternity hospital, or as a tuberculosis hospital, but does not include a sanitarium, rest home, a nursing or convalescent home, a maternity home, or an institution for treating alcoholics.

Effective: January 01, 2013

§ 4029. Hospital pharmacy defined

(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, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

Effective: January 01, 2005

§ 4030. Intern pharmacist defined

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

Effective: [See Text Amendments]

§ 4030.5. Repealed by Stats.1955, c. 1778, § 3

Effective: [See Text Amendments]

§ 4031. Laboratory defined

"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.

Effective: [See Text Amendments]

§ 4031.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4032. License defined

"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.

Effective: January 01, 2009

§ 4033. Manufacturer defined

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

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

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

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

Effective: [See Text Amendments]

§ 4033.1. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: [See Text Amendments]

§§ 4033.2, 4033.3. Repealed by Stats.1955, c. 550, § 1; Stats.1955, c. 1342, § 1

Effective: [See Text Amendments]

§§ 4033.2, 4033.3. Repealed by Stats.1955, c. 550, § 1; Stats.1955, c. 1342, § 1

Effective: [See Text Amendments]

§ 4033.5. Repealed by Stats.1955, c. 557, § 3

Effective: July 01, 2001 to December 31, 2014

§ 4034. Repealed by Stats.2000, c. 837 (A.B.1496), § 1, operative July 1, 2001

Effective: January 01, 2009

§ 4034.1. Dangerous drugs; federal regulation on pedigree or serialization measures; FDA actions inconsistent with California law; failure of board to recognize inoperation

(a)(1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(b)(1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.

(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.

(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

Effective: [See Text Amendments]

§§ 4034.5, 4034.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4034.5, 4034.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4035. Person defined

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

Effective: [See Text Amendments]

§§ 4035.1 to 4035.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4035.1 to 4035.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4035.1 to 4035.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4035.1 to 4035.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4035.1 to 4035.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2007

§ 4036. Pharmacist defined

"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.

Effective: [See Text Amendments]

§§ 4036.1 to 4036.4. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4036.1 to 4036.4. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4036.1 to 4036.4. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4036.1 to 4036.4. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2010

§ 4036.5. Pharmacist-in-charge defined

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

regulations pertaining to the practice of pharmacy.

Effective: January 01, 2011

§ 4037. Pharmacy defined

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

Effective: [See Text Amendments]

§ 4037.1. Repealed by Stats.1982, c. 1331, p. 4931, § 3, operative July 1, 1983

Effective: January 01, 2006

§ 4038. Pharmacy technician defined

(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.

Effective: [See Text Amendments]

§ 4038.1. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4038.2, 4038.3. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: [See Text Amendments]

§§ 4038.2, 4038.3. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: October 04, 2005

§ 4039. Physicians; dentists; optometrists; pharmacists; podiatrists; veterinarians; veterinary surgeons; registered nurses; naturopathic doctors; physician's assistants; definitions

"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.

Effective: January 01, 2014

§ 4040. Prescription; electronic transmission prescription; definitions

(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 or purpose for which the drug is being prescribed, if requested by the patient or patients.

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

(2) Issued by a physician, dentist, optometrist, 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 Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

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

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a

pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

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

(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.

Effective: January 01, 2000

§ 4040.5. Reverse distributor defined

"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.

Effective: [See Text Amendments]

§ 4041. Veterinary food-animal drug retailer; veterinary food animal retailer; definitions

"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.

Effective: [See Text Amendments]

§ 4042. Veterinary food-animal drugs defined

"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.

Effective: January 01, 2006

§ 4043. Wholesaler defined

(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.

Effective: January 01, 2009

§ 4044. Repackager defined

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

Effective: January 01, 2009

§ 4045. Third-party logistics provider or reverse third-party logistic provider defined

"Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

Effective: [See Text Amendments]

§§ 4046 to 4047.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4046 to 4047.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4046 to 4047.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4046 to 4047.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4046 to 4047.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4047.7. Repealed by Stats.1992, c. 485 (A.B.1226), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4047.8 to 4049.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2014

Article 3. Scope of Practice and Exemptions (Refs & Annos)

§ 4050. Professional status; health care providers

(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. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

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

Effective: [See Text Amendments]

§§ 4050.1 to 4050.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4050.1 to 4050.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4050.1 to 4050.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

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Effective: [See Text Amendments]

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Effective: [See Text Amendments]

§§ 4050.1 to 4050.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4050.1 to 4050.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2014

§ 4051. Dangerous drugs and devices

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

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

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

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

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

Effective: [See Text Amendments]

§§ 4051.1 to 4051.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4051.1 to 4051.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4051.1 to 4051.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

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Effective: [See Text Amendments]

§§ 4051.1 to 4051.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4051.1 to 4051.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2014

§ 4052. Power to perform procedures and functions; training

(a) Notwithstanding any other 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 drugs and biological products that have been ordered by a prescriber.

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

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is 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) Perform procedures or functions as authorized by Section 4052.6.

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

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

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

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

(A)(1) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

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

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

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

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

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

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

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

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

Effective: January 01, 2007

§ 4052.1. Authorized procedures performed in a health care facility

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

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

(2) Ordering drug therapy-related laboratory tests.

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

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

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

Effective: January 01, 2007

§ 4052.2. Allowed procedures if performed in accord with certain policies, procedures, or protocols

(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.

Effective: January 01, 2014

§ 4052.3. Self-administered hormonal contraceptives; emergency contraception drug therapy

(a)(1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any

prescription medication.

(b)(1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

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

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(2) Prior to performing a procedure authorized under this subdivision, 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.

(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, 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 paragraph, 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. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

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

(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications 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 Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

Effective: January 01, 2013

§ 4052.4. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for 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 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

Effective: January 01, 2002

§ 4052.5. Substituted medication; limitations imposed by prescriber; discretion of pharmacist; liability; notice to patient; prohibitions

(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.

Effective: January 01, 2014

§ 4052.6. Advanced practice pharmacists; additional practices; coordination with patient's primary care physician

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

(1) Perform patient assessments.

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

(3) Refer patients to other health care providers.

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

(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

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

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

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

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

Effective: January 01, 2002

§ 4052.7. Repackaging of drugs previously dispensed pursuant to prescriptions

(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.

Effective: January 01, 2014

§ 4052.8. Initiation and administration of vaccines; duties of pharmacist; initiation and administration of epinephrine or diphenhydramine by injection

(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

Effective: January 01, 2014

§ 4052.9. Furnishing nicotine replacement products for use by prescription; conditions

(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a

physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

Effective: January 01, 2014

§ 4053. Designated representative license; wholesaler or veterinary food-animal drug retailer supervision; requirements

(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 certificate equivalent.

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

(3) 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).

Effective: January 01, 2007

§ 4053.1. Repealed by Stats.2004, c. 857 (S.B.1307), § 8, operative Jan. 1, 2007

Effective: January 01, 2005

§ 4054. Application of § 4051; dialysis drug and device suppliers

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

Effective: [See Text Amendments]

§ 4055. Clinics and health facilities; sale of devices

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.

Effective: October 10, 1999

§ 4056. Hospitals with 100 or fewer beds; wholesale purchase of drugs; dispensing of drugs

(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.

Effective: January 01, 2000

§ 4057. Exemptions; application of chapter

(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.

Effective: [See Text Amendments]

§ 4058. Display of licenses

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.

Effective: January 01, 2011

§ 4059. Prescriptions; requirement; exceptions; penalties

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

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

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

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

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

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

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

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

Effective: January 01, 2010

§ 4059.5. Dangerous drugs and devices; license necessary to order; transfer, sale or delivery; deliveries to

hospitals and pharmacies

(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 shall sign for and receive the delivery.

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

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

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

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

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

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

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

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

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

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

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

Effective: January 01, 2014

§ 4060. Controlled substances; possession

A person shall not 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 Section 4052.1, 4052.2, or 4052.6. This section does 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, if in stock in containers correctly labeled with the name and address of the supplier or producer.

This section does not authorize a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

Effective: October 04, 2005

§ 4061. Complimentary samples

(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.

Effective: January 01, 2010

§ 4062. Federal, state, or local emergencies; dangerous drugs and devices furnished without prescription; waiver of application of provisions of this chapter or regulations; employment of mobile pharmacy

(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.

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

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

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

(3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.

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

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

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

Effective: [See Text Amendments]

§ 4063. Refills; authorization

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

Effective: [See Text Amendments]

§§ 4063.1 to 4063.11. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

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Effective: [See Text Amendments]

§§ 4063.1 to 4063.11. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4064. Refills; authorization; exception

(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.

Effective: January 01, 2013

§ 4064.5. Dangerous drugs; maximum of 90-day supply dispensed; requirements; conditions when initial supply of less than 90-days not required; notification of increase in quantity; no change to quantity specified; exceptions; health care coverage

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

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

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

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

(4) The pharmacist is exercising his or her professional judgment.

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

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

(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "No change to quantity," provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "No change to quantity," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "No change to quantity." In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.

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

(f) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

Effective: [See Text Amendments]

§ 4065. Injection card system; protocols

(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.

Effective: [See Text Amendments]

§§ 4065.1 to 4065.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4065.1 to 4065.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

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§§ 4065.1 to 4065.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4065.1 to 4065.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4065.1 to 4065.9. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4066. Ocean vessel masters and first officers; prescriptions

(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.

Effective: January 01, 2004

§ 4067. Internet; dispensing or furnishing dangerous drugs or devices; good faith prior examination

(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.

Effective: January 01, 2008

§ 4068. Dispensing dangerous drugs to emergency room patients; conditions; responsibility for error

(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.

Effective: [See Text Amendments]

§ 4069. Repealed by Stats.1937, c. 666

Effective: January 01, 2001

Article 4. Requirements for Prescriptions (Refs & Annos)

§ 4070. Oral or electronic data transmission prescription; reduction to writing; exception

(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.

Effective: [See Text Amendments]

§ 4071. Agent of prescriber; oral or electronic transmission prescriptions

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.

Effective: January 01, 2001

§ 4071.1. Electronic prescriptions or orders entered by a prescriber or pharmacist

(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.

Effective: January 01, 2011

§ 4072. Health care facilities; oral or electronic transmission of prescription

(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 State Department of Public Health in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

Effective: January 01, 2007

§ 4073. Prescriptions ordered by trade or brand name; substitutions; communication to patient

(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.

Effective: January 01, 2014

§ 4074. Informing patients of harmful effects; conditions; written label on drug container; health facilities

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

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

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

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

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

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

(e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other law shall be construed to require that only a pharmacist provide this consultation.

Effective: [See Text Amendments]

§ 4075. Controlled substances; identity of person

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.

Effective: January 01, 2014

§ 4076. Container and labeling requirements; dispensing by unit dose medication system; dangerous drugs or devices; exemption

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

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

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

file.

(iii) Dispensed medications for which no physical description exists in 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 Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

Effective: January 01, 2013

§ 4076.5. Standardized prescription drug labeling; promulgation of regulations by board; public meetings; exemptions

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

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

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

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

(2) Improved directions for use.

(3) Improved font types and sizes.

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

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

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code , if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357 , 72527, or 72528 of Title 22 of the California Code of Regulations.

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

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

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

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

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

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

Effective: [See Text Amendments]

§ 4077. Dangerous drugs; containers; labeling; DMSO

(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.

Effective: January 01, 2000

§ 4078. False or misleading labels

(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.

Effective: [See Text Amendments]

Article 5. Authority of Inspectors (Refs & Annos)

§ 4080. Dangerous drugs and devices; inspections; hours

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.

Effective: [See Text Amendments]

§§ 4080.1 to 4080.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4080.1 to 4080.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4080.1 to 4080.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4080.1 to 4080.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2010

§ 4081. Records; hours; preservation; liability for violations

(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 designated representative-in-charge, for maintaining the records and inventory described in this section.

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

Effective: [See Text Amendments]

§ 4081.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4082. Inspection; request for names of owners, managers and employees

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.

Effective: January 01, 2004

§ 4083. Order of correction; contents; service; maintenance of order on premises by licensee; authority of

board; disclosure of order under California Public Records Act

(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).

Effective: January 01, 2008

§ 4084. Adulterated, misbranded, or counterfeit dangerous drugs or devices; embargoed drugs or devices; notice; samples; definitions

(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.

Effective: [See Text Amendments]

§§ 4084.5, 4084.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4084.5, 4084.6. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2005

§ 4085. Removal, sale, or disposal of embargoed dangerous drugs or devices

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

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

Effective: January 01, 2005

§ 4086. Condemnation proceedings; adulterated or counterfeited dangerous drugs or devices; court costs and fees; destruction of drugs and devices

(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.

Effective: [See Text Amendments]

§ 4087. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4088. Repealed by Stats.1974, c. 652, p. 1515, § 3

Effective: [See Text Amendments]

§ 4089. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4089.5. Repealed by Stats.1981, c. 547, p. 2197, § 2, eff. Sept. 18, 1981

Effective: [See Text Amendments]

§§ 4090, 4091. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4090, 4091. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4092. Repealed by Stats.1979, c. 437, p. 1562, § 7

Effective: [See Text Amendments]

§§ 4093 to 4098. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4093 to 4098. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4093 to 4098. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4093 to 4098. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4093 to 4098. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4093 to 4098. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4098.1. Repealed by Stats.1978, c. 1161, p. 3666, § 247

Effective: [See Text Amendments]

§§ 4098.3, 4098.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4098.3, 4098.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4098.6. Repealed by Stats.1980, c. 559, p. 1544, § 4

Effective: [See Text Amendments]

§§ 4098.7 to 4099.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4098.7 to 4099.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4098.7 to 4099.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2006

Article 6. General Requirements (Refs & Annos)

§ 4100. Change of address; notification

(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.

Effective: January 01, 2011

§ 4101. Pharmacist-in-charge or representative-in-charge; application and approval; change of status

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

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

Effective: January 01, 2002

§ 4102. Repealed by Stats.2001, c. 501 (A.B.586), § 3

Effective: [See Text Amendments]

§ 4103. Blood pressure measurement; opinions

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.

Effective: January 01, 2012

§ 4104. Chemical, mental or physical impairments affecting pharmacy employee's ability; theft, diversion or self-use of pharmacy drugs; pharmacy procedures to protect public

(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

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

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

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

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

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

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

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

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

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

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

Effective: January 01, 2012

§ 4105. Records of acquisition and disposition of dangerous drugs and devices; location; availability; waivers; request for records by authorized officer of the law or representative of the board

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

Effective: January 01, 2006

§ 4106. License verification

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.

Effective: January 01, 2014

§ 4107. Limitations on the issuance of site licenses

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

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

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

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

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

Effective: January 01, 2010

Article 7. Pharmacies (Refs & Annos)

§ 4110. Licenses; renewal; temporary permits; fees; temporary use of mobile pharmacy; conditions

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

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

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

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

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

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

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

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

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

Effective: January 01, 2014

§ 4111. Issuance and renewal of licenses; persons or entities precluded; exceptions

(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 Section 4052.1, 4052.2, or 4052.6.

Effective: January 01, 2012

§ 4112. Nonresident pharmacies; license required; prerequisites and requirements; fee; application; contact lenses

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

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

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service

of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

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

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

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

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

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

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

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

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

Effective: January 01, 2010

§ 4113. Pharmacists-in-charge; designation; approval; responsibilities; written notifications; replacement

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

(c) 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.

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

(e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

Effective: January 01, 2006

§ 4114. Intern pharmacists

(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.

Effective: June 27, 2012

§ 4115. Pharmacy technicians; nondiscretionary tasks; direct supervision of pharmacists; registration; ratios

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

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

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of 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.

Effective: January 01, 2006

§ 4115.5. Pharmacy technician trainee externship

(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.

Effective: October 10, 1999

§ 4116. Controlled substances and dangerous drugs or devices; access; area, place or premises; security measures

(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.

Effective: [See Text Amendments]

§ 4117. Licensed hospitals; controlled substances, dangerous drugs or devices; access to area, place or premises

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.

Effective: [See Text Amendments]

§ 4118. Waivers

(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.

Effective: January 01, 2011

§ 4119. Furnishing dangerous drug or device; storage in emergency pharmaceutical supplies container

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

(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.

Effective: January 01, 2005

§ 4119.1. Pharmacy services to licensed health facilities; automated drug delivery systems; maintenance of records and operation of facility

(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.

Effective: January 01, 2002

§ 4119.2. Authority of pharmacy to furnish epinephrine auto-injectors to school district or county office of education; conditions; records

(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.

Effective: January 01, 2014

§ 4119.3. Epinephrine auto-injectors; dispensing by pharmacy for emergency care; record of receipt, use, and destruction

(a) Notwithstanding any other law, a pharmacy may dispense epinephrine auto-injectors to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

(1) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed to a person described in subdivision (b) of Section 1797.197a of the Health and Safety Code. The physician and surgeon may issue the prescription only upon presentation of a current certificate demonstrating that the person is trained and qualified under Section 1797.197a of the Health and Safety Code to administer an epinephrine auto-injector to another person in an emergency situation. The prescription shall specify that the dispensed epinephrine auto-injector is for "First Aid Purposes Only" and that the named recipient is a "Section 1797.197a Responder." A new prescription shall be written for any additional epinephrine auto-injectors required.

(2)(A) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:

(i) The name of the person to whom the prescription was issued.

(ii) The designations "Section 1797.197a Responder" and "First Aid Purposes Only."

(iii) The dosage, use, and expiration date.

(B) Each dispensed prescription shall include the manufacturer's product information sheet for the epinephrine auto-injector.

(b) The person described in subdivision (b) of Section 1797.197a of the Health and Safety Code receiving epinephrine auto-injectors pursuant to this section shall make and maintain a record for five years reflecting dates of receipt, use, and destruction of each auto-injector dispensed, the name of any person to whom epinephrine was administered using an auto-injector, and the circumstances and manner of destruction of any auto-injectors.

(c) The epinephrine auto-injectors dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.

Effective: [See Text Amendments]

§ 4119.5. Dangerous drugs and devices; transfers to other pharmacies or to prescribers

(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.

Effective: [See Text Amendments]

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(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.

Effective: [See Text Amendments]

§ 4121. Advertisements; price

(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.

Effective: January 01, 2008

§ 4122. Consumer information; posting or written receipts; prices

(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.

Effective: [See Text Amendments]

§ 4123. Parenteral therapy; compounding drugs; contracts; notification

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.

Effective: [See Text Amendments]

§ 4124. Contact lenses

(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.

Effective: January 01, 2002

§ 4125. Quality assurance program

(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.

Effective: January 01, 2002

§ 4126. Preferentially priced drugs under Section 256b; segregation from other inventory; change in circumstances; wholesaler license

(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.

Effective: January 01, 2010

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due

(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 may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) 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.

Effective: January 01, 2014

Article 7.5. Sterile Drug Products (Refs & Annos)

§ 4127. Adoption of regulations; emergency regulations

<Section operative until July 1, 2014. See, also, section operative July 1, 2014.>

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

(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.

(c) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it

becomes inoperative and is repealed.

Effective: January 01, 2014

§ 4127.1. Authority to compound injectable sterile drug products; license requirements

<Section operative until July 1, 2014. See, also, section operative July 1, 2014.>

(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 Public Health 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 requirements are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

Effective: January 01, 2014

§ 4127.2. Nonresident pharmacies; restrictions on compounding injectable sterile products for shipment into the State of California; license requirements; report to Legislature

<Section operative until July 1, 2014. See, also, section operative July 1, 2014.>

(a) A nonresident pharmacy shall 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) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(3) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(e) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

Effective: September 05, 2002

§ 4127.3. Cease and desist orders; authorization to issue orders; hearings; failure to comply with order

(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.

Effective: September 05, 2002

§ 4127.4. Violations; penalties

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.

Effective: January 01, 2010

§ 4127.5. Repealed by Stats.2009, c. 270 (A.B.1071), § 14

Effective: September 05, 2002

§ 4127.6. Operative date of Article

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.

Effective: January 01, 2005

§ 4127.7. Compounding sterile injectable products; environments

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.

Effective: January 01, 2010

§ 4127.8. Temporary licenses; fees; terms and conditions; termination; vested right or interest

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

Effective: January 01, 2014

§ 4127.9. Pharmacies issuing recall notice regarding sterile compounds; duties; notice requirements

(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

Effective: January 01, 2013

Article 7.6. Centralized Hospital Packaging Pharmacies (Refs & Annos)

§ 4128. Hospitals under common ownership; extent of pharmacy authority to prepare medications

(a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(2) Preparing compounded unit dose drugs for parenteral therapy for administration to inpatients, if each compounded unit dose drug is barcoded to contain at least the information required by Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

Effective: January 01, 2013

§ 4128.2. Speciality license; application; inspection; licensure as hospital pharmacy; annual renewal; fee

(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) The fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars ($600) and may be increased by the board to eight hundred dollars ($800).

Effective: January 01, 2013

§ 4128.3. Preparation and storage of unit dose drugs

A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of inpatients of the general acute care hospital based on a documented history of prescriptions for that patient population.

Effective: January 01, 2013

§ 4128.4. Unit dose medications; barcoded information

Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

(a) The date the medication was prepared.

(b) The components used in the drug product.

(c) The lot number or control number.

(d) The expiration date.

(e) The National Drug Code Directory number.

(f) The name of the centralized hospital packaging pharmacy.

Effective: January 01, 2013

§ 4128.5. Labeling for unit dose medications

The label for each unit dose medication produced by a centralized hospital packaging pharmacy shall contain all of the following:

(a) The expiration date.

(b) The established name of the drug.

(c) The quantity of the active ingredient.

(d) Special storage or handling requirements.

Effective: January 01, 2013

§ 4128.6. Compliance with state and federal law and regulations

All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile injectable compounding.

Effective: January 01, 2013

§ 4128.7. Responsibility for unit dose drug products

A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

Effective: July 01, 2001

Article 8. Medical Device Retailers [Repealed] (Refs & Annos)

§§ 4130 to 4132. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4130 to 4132. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4130 to 4132. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: [See Text Amendments]

§ 4132.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: July 01, 2001

§§ 4133, 4134. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4133, 4134. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: [See Text Amendments]

§ 4134.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: July 01, 2001

§§ 4135 to 4138. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4135 to 4138. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4135 to 4138. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4135 to 4138. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2001

§§ 4135 to 4138. Repealed by Stats.2000, c. 837 (A.B.1496), § 12, operative July 1, 2001

Effective: July 01, 2002

§ 4139. Repealed by Stats.2000, c. 837 (A.B.1496), § 13, operative Jan. 1, 2003

Effective: January 01, 2012

Article 9. Hypodermic Needles and Syringes (Refs & Annos)

§ 4140. Repealed by Stats.2011, c. 738 (S.B.41), § 2

Effective: [See Text Amendments]

§ 4140.5. Repealed by Stats.1985, c. 613, § 1

Effective: [See Text Amendments]

§ 4140.7. Repealed by Stats.1985, c. 613, § 1

Effective: [See Text Amendments]

§ 4141. Sales and other modes of distribution; license

No person shall furnish hypodermic needles or syringes, by sale or otherwise, without a license issued by the board, except as otherwise provided by this article.

Effective: October 04, 2005

§ 4142. Retail sales; prescription

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.

Effective: [See Text Amendments]

§ 4143. Application of article

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.

Effective: January 01, 2012

§ 4144. Hypodermic needles and syringes; inoperability

<Section inoperative until Jan. 1, 2015. See, also, similar provisions contained at § 4144.5, operative until Jan. 1, 2015.>

(a) 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.

(b) This section shall be inoperative until January 1, 2015.

Effective: January 01, 2012

§ 4144.5. Sale without prescription or permit for industrial use; repeal

<Section operative until Jan. 1, 2015. See, also, similar provisions contained at § 4144, inoperative until Jan. 1, 2015.>

(a) A person may sell or obtain hypodermic needles and hypodermic syringes without a prescription or permit, for uses that the board determines are industrial, and that person shall not be required to comply with Section 4145.5 or 4146.

(b) This section 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 that date.

Effective: January 01, 2012

§ 4145. Furnishing for human use without a prescription or license; requirements; furnishing for use on animals; inoperability

<Section inoperative until Jan. 1, 2015. See, also, similar provisions contained at § 4145.5, operative until Jan. 1, 2015.>

(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, 2018, 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 with 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.

(c) This section shall be inoperative until January 1, 2015.

Effective: January 01, 2012

§ 4145.5. Furnishing for human use without a prescription or license; furnishing as public health measure; furnishing for use on animals; storage; disposal options; consumer information; repeal

<Section operative until Jan. 1, 2015. See, also, similar provisions contained at § 4145, inoperative until Jan. 1, 2015.>

(a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the 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.

(b) Notwithstanding any other provision of law, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on 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.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets

applicable state and federal standards for collection and disposal of medical sharps waste.

(2) It shall furnish, or make available, mail-back sharps containers authorized by the United States Postal Service that meet applicable state and federal requirements for the transport of medical sharps waste, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(f) A pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

(g) This section 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 that date.

Effective: January 01, 2010

§ 4146. Return of needles and syringes

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container, as defined in Section 117750 of the Health and Safety Code.

Effective: January 01, 2005

§ 4147. Disposal requirements; illegal disposal at certain locations; misdemeanor; exception

(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.

Effective: January 01, 2012

§ 4148. Confiscation; stocks outside of licensed premises and not in possession or control of authorized person; inoperability

<Section inoperative until Jan. 1, 2015. See, also, similar provisions contained at § 4148.5, operative until Jan. 1, 2015.>

(a) 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.

(b) This section shall be inoperative until January 1, 2015.

Effective: January 01, 2012

§ 4148.5. Confiscation; stocks outside of licensed premises and not in possession or control of authorized person

<Section operative until Jan. 1, 2015. See, also, similar provisions contained at § 4148, inoperative until Jan. 1, 2015.>

(a) 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 4145.5, or under Section 11364.5, 121349, or 121349.1 of the Health and Safety Code.

(b) This section 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 that date.

Effective: [See Text Amendments]

§ 4149. Nonresident distributor's license

(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.

Effective: January 01, 2012

§ 4149.5. Local authorizations; inoperability; duration

(a) Local authorizations related to Sections 4144, 4145, and 4148 of this code and Sections 11364 and 121285 of the Health and Safety Code shall be inoperative until January 1, 2015.

(b) Local authorizations related to Sections 4144, 4145, and 4148 of this code and Sections 11364 and 121285 of the Health and Safety Code shall again become operative on January 1, 2015, unless the city, county, or city and county acts to remove the authorization.

Effective: [See Text Amendments]

Article 10. Pharmacy Corporations (Refs & Annos)

§ 4150. Authorized corporations; Board of Pharmacy

(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.

Effective: [See Text Amendments]

§ 4151. Shareholders, directors and officers; necessity of licensure

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.

Effective: [See Text Amendments]

§ 4152. Name

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.

Effective: [See Text Amendments]

§ 4153. Disqualified shareholder; income

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.

Effective: [See Text Amendments]

§ 4154. Regulations; bylaws; insurance

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.

Effective: [See Text Amendments]

§ 4155. Construction of article

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.

Effective: [See Text Amendments]

§ 4156. Unprofessional conduct

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.

Effective: January 01, 2010

Article 11. Wholesalers and Manufacturers (Refs & Annos)

§ 4160. Licenses

(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) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler.

(e) Every wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the

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

(f) 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.

(g) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for 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.

Effective: January 01, 2010

§ 4161. Out-of-state distributors; licensing; renewal; reported information; compliance with directions and requests for information; records; temporary licenses; fees

(a) A person located outside this state that (1) ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, selling, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, or distributing dangerous drugs or devices within 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, sold, mailed, or delivered to a site located in this state or sold, brokered, or distributed within 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 or within 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.

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

Effective: January 01, 2009

§ 4162. Submission of surety bond for issuance or renewal of wholesaler license; exemptions; claims against bonds

(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.

Effective: January 01, 2009

§ 4162.5. Submission of surety bond; purpose; acceptance of bond; claims against bond

(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.

Effective: January 01, 2009

§ 4163. Dangerous drugs or devices furnished to unauthorized persons; obligations of wholesalers, repackagers, or pharmacies

(a) A manufacturer, wholesaler, repackager, or pharmacy 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 July 1, 2016, a wholesaler or repackager 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 July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.

(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a "pharmacy warehouse" means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

Effective: January 01, 2007

§ 4163.1. Information regarding manufacturer's specific relationships with wholesalers; legislative intent

<Section added by Stats.2006, c. 658 (S.B.1476), § 68. See, also, another section of the same number added by Stats.2008, c. 713 (S.B.1307), § 9.>

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.

Effective: January 01, 2009

§ 4163.1. Drop shipment

<Section added by Stats.2008, c. 713 (S.B.1307), § 9. See, also, another section of the same number added by Stats.2006, c. 658 (S.B.1476), § 68.>

(a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

Effective: January 01, 2009

§ 4163.2. Dangerous drugs designated as not subject to pedigree requirements; written declaration

(a)(1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

Effective: January 01, 2009

§ 4163.3. Legislative intent; maintaining integrity of pedigree system; use of inference

(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against

those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Effective: January 01, 2009

§ 4163.4. Exemption from pedigree requirements

(a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

Effective: January 01, 2009

§ 4163.5. Legislative findings and declarations; system benefits; compliance

(a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all

prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:

(1) Unit volume.

(2) Product package (SKU) type.

(3) Drug product family.

(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

Effective: January 01, 2007

§ 4163.6. Repealed by Stats.2006, c. 658 (S.B.1476), § 70

Effective: January 01, 2006

§ 4164. Sale of dangerous drugs and controlled substances; reports; tracking system; definitions

(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.

Effective: January 01, 2005

§ 4165. Sale or transfer of dangerous drugs or devices; requests for records by law officers

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.

Effective: January 01, 2005

§ 4166. Use of carrier; liability for security and integrity of dangerous drugs or devices

(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.

Effective: [See Text Amendments]

§ 4167. Security of dangerous drugs or devices on wholesaler's premises

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.

Effective: January 01, 2005

§ 4168. Issuance of business licenses; establishments

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.

Effective: January 01, 2011

§ 4169. Prohibited activities; violations; application of section

(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 Public Health.

Effective: October 04, 2005

Article 12. Prescriber Dispensing (Refs & Annos)

§ 4170. Conditions; enforcement of chapter; prescriber

(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.

Effective: January 01, 2005

§ 4170.5. Veterinary teaching hospitals; dispensing and administering dangerous drugs, devices and controlled substances; responsible pharmacist; development of policies, procedure and guidelines; inspections

(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.

Effective: January 01, 2004

§ 4171. Exemptions; samples

(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.

Effective: [See Text Amendments]

§ 4172. Storage of drugs; secure area

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.

Effective: [See Text Amendments]

§ 4173. Registered nurses; application of chapter

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

Effective: January 01, 2014

§ 4174. Orders to dispense drugs or devices

Notwithstanding any other 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 4052.1, 4052.2, 4052.3

, or 4052.6.

Effective: October 04, 2005

§ 4175. Complaints relating to dispensing of dangerous drugs or devices

(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.

Effective: [See Text Amendments]

§ 4176. Repealed by Stats.1979, c. 437, § 28

Effective: [See Text Amendments]

§ 4177. Repealed by Stats.1979, c. 437, § 29

Effective: [See Text Amendments]

§ 4178. Repealed by Stats.1979, c. 437, § 30

Effective: [See Text Amendments]

§ 4179. Repealed by Stats.1979, c. 437, § 31

Effective: January 01, 2007

Article 13. Nonprofit or Free Clinics (Refs & Annos)

§ 4180. Purchase, administration and dispensing of drugs; records; license required

(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.

Effective: January 01, 2011

§ 4181. Policies and procedures; compliance with applicable laws and regulations; dispensing drugs

(a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

Effective: January 01, 2007

§ 4182. Pharmacy services; professional director's responsibilities; consulting pharmacist visits; certification; definitions; change in director

(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.

Effective: [See Text Amendments]

§ 4183. Dispensing fees; Medi-Cal program

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).

Effective: [See Text Amendments]

§ 4184. Schedule II controlled substances

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.

Effective: [See Text Amendments]

§ 4185. Inspections

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.

Effective: January 01, 2002

§ 4186. Locating automated drug delivery systems in licensed clinics; policies and procedures; removal, stocking, review and labeling of drugs; patient consultation; location of pharmacists

(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.

Effective: January 01, 2013

Article 14. Clinics (Refs & Annos)

§ 4190. Purchase, administration and dispensing of drugs; records; drug distribution services; license required; change in ownership or beneficial interest; ability of physician and surgeon not limited

(a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) A clinic licensed by the board may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(c) The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board.

(e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) Nothing in this section shall limit the ability of a physician and surgeon to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.

Effective: January 01, 2011

§ 4191. Policies and procedures; compliance with applicable laws and regulations; dispensing drugs

(a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

Effective: January 01, 2007

§ 4192. Pharmacy services; professional director's responsibilities; certification; definitions; change in director

(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.

Effective: [See Text Amendments]

§ 4193. Dispensing fees; Medi-Cal program; sale of drugs; charges for professional services in dispensing or administration of drugs

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.

Effective: [See Text Amendments]

§ 4194. Schedule II controlled substances

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.

Effective: January 01, 2013

§ 4195. Inspections

The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law.

Effective: January 01, 2011

Article 15. Veterinary Food-Animal Drug Retailers (Refs & Annos)

§ 4196. Licenses; persons allowed in areas where drugs stored, possessed, or repacked; designated representative-in-charge

(a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to

be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) Every veterinary food-animal drug retailer shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge who ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

Effective: [See Text Amendments]

§ 4197. Minimum standards; waivers

(a) The following minimum standards shall apply to all veterinary food-animal drug retailers licensed by the board:

(1) Each retailer shall store veterinary food-animal drugs in a secure, lockable area.

(2) Each retailer shall maintain on the premises fixtures and equipment in a clean and orderly condition. The premises shall be dry, well-ventilated, and have adequate lighting.

(b) The board may, by regulation, impose any other minimum standards pertaining to the acquisition, storage, and maintenance of veterinary food-animal drugs, or other goods, or to the maintenance or condition of the licensed premises of any veterinary food-animal drug retailer as the board determines are reasonably necessary.

(c) When, in the opinion of the board, a high standard of patient safety consistent with good animal safety and care in the case of an animal patient can be provided by the licensure of a veterinary food-animal drug retailer that does not meet all of the requirements for licensure as a veterinary food-animal drug retailer, the board may waive any licensing requirements.

Effective: [See Text Amendments]

§ 4198. Drugs; handling and dispensing; policies and procedures; quality assurance program; records; consulting pharmacist visits; certification

(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.

Effective: [See Text Amendments]

§ 4199. Prescriptions; labeling requirements; records

(a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to this chapter is subject to the labeling requirements of Sections 4076 and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

Effective: January 01, 2012

Article 16. Applications (Refs & Annos)

§ 4200. Qualifications; proof; fees

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2)(A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed 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.

Effective: January 01, 2011

§ 4200.1. North American Pharmacist Licensure Examination; California Practice Standards and Jurisprudence Examination for Pharmacists; limits on reexaminations; applicant requirements; coursework; treatment of failing score

(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 a 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.

Effective: January 01, 2008

§ 4200.2. Development of California Practice Standards and Jurisprudence Examination for Pharmacists; contents

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.

Effective: January 01, 2010

§ 4200.3. Examination process; review; standards; compliance with nondiscrimination mandates; annual publication of pass and fail rates; report of comparison of state applicants' pass and fail rates with those of national examination applicants

(a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board

shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Professional Examination Services or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection and the department as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

Effective: January 01, 2010

§ 4200.4. Failure of national examination; mandatory period of time prior to retaking examination

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 Professional Examination Services of the department.

Effective: January 01, 2002

§ 4200.5. Retired licenses

(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.

Effective: July 01, 2001

§ 4201. Contents of applications; fees; powers of license holders

(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.

Effective: January 01, 2006

§ 4202. Pharmacy technicians; certification; qualifications; background check; suspension and revocation

(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.

Effective: [See Text Amendments]

§ 4203. Nonprofit or free clinics; forms; investigation; issuance

(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.

Effective: [See Text Amendments]

§ 4204. Surgical clinics; forms; contents; investigation; issuance

(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.

Effective: January 01, 2006

§ 4205. Hypodermic needles and syringes; licenses; forms; denial, revocation or suspension

(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.

Effective: January 01, 2006

§ 4206. Repealed by Stats.2005, c. 621 (S.B.1111), § 59

Effective: January 01, 2012

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

Effective: January 01, 2008

§ 4208. Issuance of intern pharmacist license; return of license; extension of license

(a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license shall be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) A person who has not completed the experience requirements necessary to be eligible for the licensure examination may have his or her intern license extended for a period of up to two years at the discretion of the board if he or she is able to demonstrate his or her inability to exercise the privileges of the intern license during the initial license period.

Effective: January 01, 2013

§ 4209. Required hours of pharmacy practice; application for pharmacist licensure examination; compliance with Standards of Curriculum; certification

(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. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. 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.

Effective: January 01, 2014

§ 4210. Advanced practice pharmacists; requirements; duration of recognition; regulations

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following

requirements:

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

(2) Satisfy any two of the following criteria:

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

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

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

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

(4) Pay the applicable fee to the board.

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

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

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

Effective: [See Text Amendments]

§§ 4211, 4211.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4211, 4211.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4212. Renumbered § 4048.5 and amended by Stats.1965, c. 1822, p. 4204, § 18

Effective: [See Text Amendments]

§ 4213. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4214. Renumbered § 4049 and amended by Stats.1965, c. 1822, p. 4205, § 19

Effective: [See Text Amendments]

§ 4215. Repealed by Stats.1965, c. 1822, p. 4205, § 20

Effective: [See Text Amendments]

§ 4216. Repealed by Stats.1965, c. 1822, p. 4205, § 21

Effective: [See Text Amendments]

§ 4217. Repealed by Stats.1965, c. 1822, p. 4205, § 22; Stats.1968, c. 1463, p. 2925, § 7, operative July 1, 1969

Effective: [See Text Amendments]

§ 4218. Repealed by Stats.1965, c. 1822, p. 4205, § 23

Effective: [See Text Amendments]

§ 4219. Repealed by Stats.1965, c. 1822, p. 4205, § 24

Effective: [See Text Amendments]

§ 4220. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4221. Renumbered § 4049.5 and amended by Stats.1965, c. 1822, p. 4205, § 25

Effective: [See Text Amendments]

§ 4221.5. Renumbered § 4014 and amended by Stats.1965, c. 1822, p. 4205, § 26

Effective: [See Text Amendments]

§ 4222. Repealed by Stats.1970, c. 1596, § 2

Effective: [See Text Amendments]

§ 4223. Repealed by Stats.1970, c. 1596, § 3

Effective: [See Text Amendments]

§ 4224. Repealed by Stats.1970, c. 1596, § 4

Effective: [See Text Amendments]

§ 4225. Repealed by Stats.1970, c. 1596, § 5

Effective: [See Text Amendments]

§ 4226. Repealed by Stats.1970, c. 1596, § 6

Effective: [See Text Amendments]

§ 4226.5. Repealed by Stats.1970, c. 1596, § 7

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4227 to 4229.5. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

Article 17. Continuing Education (Refs & Annos)

§ 4230. Repealed by Stats.1997, c. 549 (S.B.1349), § 109

Effective: [See Text Amendments]

§ 4230.5. Renumbered § 4390.5 and amended by Stats.1965, c. 1822, p. 4206, § 29

Effective: January 01, 2010

§ 4231. Renewal certificates; proof of successful completion of courses

(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.

(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

Effective: January 01, 2006

§ 4232. Courses; form and subject matter

(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.

Effective: January 01, 2014

§ 4233. Advanced practice pharmacists; additional hours

A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

Effective: [See Text Amendments]

§ 4234. Exceptions; emergency and hardship cases

The board may, in accordance with the intent of this article, make exceptions from the requirements of this article in emergency or hardship cases.

Effective: [See Text Amendments]

§ 4235. Repealed by Stats.1980, c. 649, p. 1820, § 13

Effective: [See Text Amendments]

§ 4236. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4237. Repealed by Stats.1965, c. 1822, p. 4206, § 32

Effective: [See Text Amendments]

§§ 4238 to 4239. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4238 to 4239. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4238 to 4239. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

Article 18. Poisons (Refs & Annos)

§ 4240. Applicability of Hazardous Substances Act; enforcement; poison

(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.

Effective: [See Text Amendments]

§§ 4241, 4242. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4241, 4242. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4250 to 4256. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: [See Text Amendments]

§§ 4250 to 4256. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: [See Text Amendments]

§§ 4250 to 4256. Repealed by Stats.1955, c. 550, p. 1027, § 1

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Effective: [See Text Amendments]

§§ 4250 to 4256. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: [See Text Amendments]

§§ 4250 to 4256. Repealed by Stats.1955, c. 550, p. 1027, § 1

Effective: [See Text Amendments]

Article 19. Disciplinary Proceedings (Refs & Annos)

§ 4300. Licenses; methods of discipline; unprofessional conduct; probationary status; proceedings under this article

(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.

Effective: January 01, 2013

§ 4300.1. Jurisdiction of board to commence or proceed with investigation, action, or disciplinary proceeding; not affected by expiration, cancellation, forfeiture, suspension, placement on retired status, or voluntary surrender

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary

surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

Effective: January 01, 2010

§ 4301. Unprofessional conduct; licenses procured through misrepresentation, fraud, or mistake

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. For purposes of this section, "long-term care facility" shall have the same meaning given the term in

Section 1418 of the Health and Safety Code.

Effective: [See Text Amendments]

§ 4301.5. Out-of-state or federal license or authority; suspension or revocation

(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.

Effective: [See Text Amendments]

§ 4302. Pharmacy corporations; denial, suspension or revocation of license; shareholders, officers and directors

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.

Effective: January 01, 2014

§ 4303. Nonresident pharmacy; violation; cancellation, revocation, or suspension of license

(a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

Effective: [See Text Amendments]

§ 4304. Out-of-state manufacturers, wholesalers or pharmacies; violations of Sherman food, drug, and cosmetics law

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.

Effective: January 01, 2010

§ 4305. Pharmacist-in-charge; failure to notify board of cessation of acting in that capacity; operation of pharmacy without pharmacist-in-charge; grounds for disciplinary action

(a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act as the pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in Sections 4101 and 4113 shall constitute grounds for disciplinary action.

(b) Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

Effective: January 01, 2006

§ 4305.5. Termination of employment of pharmacists or exemptees acting as managers; duty to notify board; penalties

(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.

Effective: [See Text Amendments]

§ 4306. Unprofessional conduct; violations of article, Moscone-Knox professional corporation act or regulations

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.

Effective: January 01, 2007

§ 4306.5. Acts or omissions constituting unprofessional conduct

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

Effective: January 01, 2003

§ 4306.6. Pharmacist-in-charge; disciplinary action based on violations committed by another person; report of violation by pharmacist-in-charge as mitigating factor; conditions

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.

Effective: [See Text Amendments]

§ 4307. Persons prohibited from serving in ownership or managerial positions; pleadings

(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.

Effective: [See Text Amendments]

§ 4308. Notice; prohibition against serving in ownership or managerial positions; change of permit

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.

Effective: [See Text Amendments]

§ 4309. Reinstatement or modification of penalty; petitions; conditions; hearings

(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.

Effective: [See Text Amendments]

§ 4310. Denial of application; notice; petition; proceedings

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.

Effective: January 01, 2005

§ 4311. Felony convictions; incarceration; license suspension; notice; hearing

(a) Any license issued by the board, or the holder thereof, shall be suspended automatically during any time that the person is incarcerated after conviction of a felony, regardless of whether the conviction has been appealed. The board, immediately upon receipt of a certified copy of a record of a criminal conviction, shall determine whether the person has been automatically suspended by virtue of incarceration pursuant to a felony conviction and, if so, the duration of that suspension. The board shall notify the person so suspended of the suspension and that the person has a right to request a hearing, solely as to whether he or she is incarcerated pursuant to a felony conviction, in writing at that person's address of record with the board and at the facility in which the person is incarcerated.

(b) In addition to any suspension under subdivision (a), the board shall summarily suspend any license issued by the board where a conviction of the holder of the license meets the requirements of paragraphs (1) and (2).

(1) A felony that was either of the following:

(A) Committed in the course of a business or practice for which the board issues a license.

(B) Committed in a manner that a client, customer, or patient of the licensee was a victim.

(2) Where an element of the offense involves either of the following:

(A) The specific intent to deceive, defraud, steal, or make a false statement.

(B) The illegal sale or possession for sale of or trafficking in any controlled substance.

(3) The suspension shall continue until the time for appeal has elapsed, if no appeal is taken, or until the judgment of conviction has been affirmed on appeal or has otherwise become final, and until further order of the board.

(4) The board shall immediately send notice in writing of the suspension to the licensee, or the holder of any other board-issued license, at his or her address of record and, if incarcerated at the time, at the facility in which the person is incarcerated. The notice shall include notification of that person's right to elect to have the issue of penalty heard as provided in paragraph (2) of subdivision (d), and of the right to request a hearing to contest the summary suspension. Any request for a hearing under this paragraph must be received by the board within 15 days following receipt of the notice provided for by this paragraph.

(5) The hearing shall be before an administrative law judge, a committee of the board sitting with an administrative law judge, or the board sitting with an administrative law judge, at the board's discretion, and shall be subject to review by the board, at its discretion. The hearing shall be limited to (A) whether there has been a felony conviction as stated in the board's notice, and (B) whether the conviction meets the criteria of this subdivision, except where the licensee chooses to proceed as provided by paragraph (2) of subdivision (d), or where the board has also filed and served an accusation as provided in Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of the hearing as required by that chapter; provided that if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case.

(c) In addition to any suspension under subdivision (a), the board shall also suspend any license issued by the board, or the holder thereof, if the board determines that the felony conviction of the holder of the license is substantially related to the qualifications, functions, or duties of the licensee.

(1) Notice of the board's determination shall be sent to the licensee, or the holder thereof, at that person's address of record with the board and, if the person is incarcerated at the time, the facility in which the person is incarcerated. The notice shall advise the person that the license shall be suspended without hearing unless, within 15 days following receipt of the notice, a written request for hearing is delivered to the board.

(2) Upon receipt of a timely request for hearing, a notice of hearing shall be sent to the person at least 10 days before the date scheduled for the hearing. The notice of hearing shall include notification of that person's right to elect to have the issue of penalty heard as provided in paragraph (2) of subdivision (d).

(3) The hearing to determine whether a felony conviction is substantially related for purposes of an interim

suspension under this subdivision shall be separate from any hearing on an accusation under the Administrative Procedure Act, except where the licensee elects to proceed under paragraph (2) of subdivision (d), or where the board has filed and served an accusation as provided by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of hearing as required by that chapter. The hearing on whether the felony conviction is substantially related shall be heard either by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law judge, or by the board sitting with an administrative law judge, at the board's discretion, and shall be subject to review by the board, at its discretion. However, if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case. Except where a person proceeds under paragraph (2) of subdivision (d), or the board proceeds with an accusation at the same time, any suspension imposed under this subdivision shall continue until an accusation is filed under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and a final decision is rendered by the board.

(4) A conviction of any crime referred to in Section 4301, or for violation of Section 187, 261, or 288 of the Penal Code, shall be conclusively presumed to be substantially related to the qualifications, functions, or duties of a licensee of the board. Upon its own motion or for good cause shown the board may decline to impose a suspension under this subdivision or may set aside a suspension previously imposed when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the practice of pharmacy and the handling of dangerous drugs and devices.

(d)(1) Discipline may be ordered in accordance with Section 4300 or an application denied when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, setting aside the verdict of guilty, or dismissing the accusation, complaint, information, or indictment.

(2) The issue of penalty shall be heard by an administrative law judge sitting alone or with a committee of the board or with the board itself, at the board's discretion, and any decision shall be subject to review by the board, at its discretion. The hearing shall not be held until the judgment of conviction has become final or, irrespective of a subsequent order under Section 1203.4 of the Penal Code, an order granting probation has been made suspending the imposition of sentence, provided that a licensee may, at his or her option, elect to have the issue of penalty decided before those time periods have elapsed. Where the licensee so elects, the issue of penalty shall be heard in the manner described in this section at the hearing to determine whether the conviction was substantially related to the qualifications, functions, or duties of the licensee. If the conviction of a licensee who has made this election is overturned on appeal, any discipline ordered pursuant to this section shall automatically cease. Nothing in this subdivision shall prohibit the board from pursuing disciplinary action based on any cause, including the facts underlying the conviction, other than the overturned conviction.

(3) The record of the proceedings resulting in the criminal conviction, including a transcript of any testimony taken in connection with the proceeding, may be received in evidence in any administrative proceeding to the extent the testimony would otherwise be admissible under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. A certified copy of the criminal conviction shall be conclusive proof of the fact of the conviction.

(e) Other provisions of this chapter setting forth procedures for the suspension or revocation of a license issued by the board shall not apply to proceedings conducted pursuant to this section, except as specifically provided in this section.

(f) For purposes of this section, a crime is a felony if it is specifically declared to be so or is made a felony by subdivision (a) of Section 17 of the Penal Code, unless it is charged as a misdemeanor pursuant to paragraph (4) or (5) of subdivision (b) of Section 17 of the Penal Code, irrespective of whether in a particular case the crime may be considered a misdemeanor as a result of postconviction proceedings. For purposes of this section, a felony also includes a conviction under federal law, or the law of any other state of the United States, of the District of Columbia, or of any territory or possession of the United States. A conviction includes a plea or verdict of guilty or a conviction following a plea of nolo contendere.

(g) The board may delegate the authority to issue a suspension under subdivision (a) or (b) or a notice of suspension under subdivision (c) to the executive officer of the board.

Effective: January 01, 2004

§ 4312. Licensed premises remaining closed; cancelling license; procedure; transfer of dangerous drugs, devices, and controlled substances; procedure upon failure to comply

(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.

Effective: [See Text Amendments]

§ 4313. Rehabilitation and public protection considerations; board decisions

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.

Effective: January 01, 2008

§ 4314. Authority of board to issue citations containing fines and orders of abatement; administrative fines; scope of section

(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.

Effective: January 01, 2008

§ 4315. Letters of admonishment

(a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733, for failure to comply with this chapter or regulations adopted pursuant to this chapter, or for failure to comply with Division 116 (commencing with Section 150200) of the Health and Safety Code, directing the licensee to come into compliance.

(b) The 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).

Effective: [See Text Amendments]

§§ 4316 to 4319. Repealed by Stats.1980, c. 796, p. 2405, § 2

Effective: [See Text Amendments]

§§ 4316 to 4319. Repealed by Stats.1980, c. 796, p. 2405, § 2

Effective: [See Text Amendments]

§§ 4316 to 4319. Repealed by Stats.1980, c. 796, p. 2405, § 2

Effective: [See Text Amendments]

§§ 4316 to 4319. Repealed by Stats.1980, c. 796, p. 2405, § 2

Effective: [See Text Amendments]

Article 20. Prohibitions and Offenses (Refs & Annos)

§ 4320. Civil actions; county district attorney or city attorney

(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.

Effective: [See Text Amendments]

§ 4321. Violations generally; offense; punishment

(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).

Effective: [See Text Amendments]

§ 4322. False representations; licensure or registration; punishment

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.

Effective: [See Text Amendments]

§ 4323. False representation as authorized prescriber; telephone or electronic communications; punishment

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.

Effective: [See Text Amendments]

§§ 4323.5. Repealed by Stats.1980, c. 796, p. 2405, § 2

Effective: October 01, 2011

§ 4324. Forged prescriptions; possession of drugs obtained by forged prescription; punishment

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in the county jail for not more than one year.

Effective: [See Text Amendments]

§ 4325. Prescription blanks; manufacture, reproduction or possession

(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.

Effective: [See Text Amendments]

§ 4326. False representations; hypodermic needle or syringe; unintended use

(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.

Effective: [See Text Amendments]

§ 4327. Operation under influence of drugs or alcohol; sale, dispensing or compounding drugs

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.

Effective: [See Text Amendments]

§ 4328. Unauthorized persons compounding, dispensing or furnishing dangerous drugs

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.

Effective: January 01, 2010

§ 4329. Nonpharmacists; prohibited acts

Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

Effective: January 01, 2010

§ 4330. Proprietors; prohibited acts

(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) Any pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

Effective: January 01, 2006

§ 4331. Unauthorized conduct of wholesalers or retailers; furnishing of devices, or dispensation of prescriptions; punishment

(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.

Effective: [See Text Amendments]

§ 4332. Dangerous drugs or devices; records; failure to maintain; failure to produce; falsification

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.

Effective: [See Text Amendments]

§ 4333. Prescriptions and other records; maintenance; willful violations; punishment; waivers

(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.

Effective: [See Text Amendments]

§ 4335. Violations of Business and Professions Code § 4312(b)

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

Effective: [See Text Amendments]

§ 4336. Minors; use as agent; dangerous drugs

(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.

Effective: [See Text Amendments]

§ 4337. Fines collected under chapter; allocation

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.

Effective: [See Text Amendments]

§ 4338. Fines; AIDS education program

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.

Effective: [See Text Amendments]

§ 4339. Injunctions; procedure

(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.

Effective: [See Text Amendments]

§ 4340. Advertisements; nonresident pharmacies

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.

Effective: [See Text Amendments]

§ 4341. Advertisements; prescription drugs or devices

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

Effective: [See Text Amendments]

§ 4342. Actions necessary to prevent sale of nonconforming pharmaceuticals or violations of Sherman Food, Drug and Cosmetic Law; violations of regulations adopted pursuant to Business and Professions Code § 4006

(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.

Effective: [See Text Amendments]

§ 4343. Pharmacy; building; signs or displays; words and characters used

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.

Effective: July 01, 2001

§ 4344. Repealed by Stats.2000, c. 837 (A.B.1496), § 22, operative July 1, 2001

Effective: [See Text Amendments]

§§ 4350 to 4351. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4350 to 4351. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4350 to 4351. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

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§§ 4350 to 4351. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4350 to 4351. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4352. Repealed by Stats.1965, c. 1822, p. 4207, § 39

Effective: [See Text Amendments]

§§ 4353 to 4355. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4353 to 4355. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4353 to 4355. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4356, 4357. Repealed by Stats.1965, c. 1822, p. 4208, §§ 44, 45

Effective: [See Text Amendments]

§§ 4356, 4357. Repealed by Stats.1965, c. 1822, p. 4208, §§ 44, 45

Effective: [See Text Amendments]

§§ 4358, 4359. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4358, 4359. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2006

Article 21. Pharmacists Recovery Program (Refs & Annos)

§ 4360. Pharmacists recovery program; purpose

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.

Effective: January 01, 2006

§ 4361. Definitions

(a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

Effective: January 01, 2006

§ 4362. Entry into program; referral or election; discipline or other enforcement action

(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.

Effective: January 01, 2006

§ 4363. Repealed by Stats.2005, c. 621 (S.B.1111), § 68

Effective: January 01, 2006

§ 4364. Participation criteria

(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.

Effective: January 01, 2006

§ 4365. Contract for administration of program

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

Effective: January 01, 2006

§ 4366. Functions of contractor administering the program

The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:

(a) To evaluate those pharmacists and intern pharmacists who request participation in the program.

(b) To develop a treatment contract with each participant in the pharmacists recovery program.

(c) To monitor the compliance of each participant with their treatment contract.

(d) To prepare reports as required by the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

Effective: January 01, 2006

§ 4367. Repealed by Stats.2005, c. 621 (S.B.1111), § 72

Effective: January 01, 2006

§ 4368. Repealed by Stats.2005, c. 621 (S.B.1111), § 73

Effective: January 01, 2006

§ 4369. Effect of failure to comply with program requirements; participation as defense to disciplinary action

(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.

Effective: January 01, 2006

§ 4370. Repealed by Stats.2005, c. 621 (S.B.1111), § 75

Effective: January 01, 2009

§ 4371. Program manager; duties

(a) The executive officer of the board shall designate a program manager of the pharmacists recovery program. The program manager shall have background experience in dealing with substance abuse issues.

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

(c) The program manager shall work with the contractor administering the pharmacists recovery program to evaluate participants in the program according to established guidelines and to develop treatment contracts and evaluate participant progress in the program.

Effective: January 01, 2006

§ 4372. Confidentiality of records

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.

Effective: January 01, 2006

§ 4373. Personal liability

No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

Effective: [See Text Amendments]

Article 22. Unfair Trade Practices (Refs & Annos)

§ 4380. Drugs acquired at preferentially low prices; resale; exceptions

(a) The resale, by any person, of drugs acquired at preferentially low prices permitted under federal law only because of the Nonprofit Institutions Act (15 U.S.C. Sec. 13c) is prohibited except in any of the following instances:

(1) When for the person's own use, as defined by the federal courts in Abbott Labs. v. Portland Retail Druggists (425 U.S. 1, 47 L.Ed.2d 537) and DeModena v. Kaiser Foundation Health Plan, Inc. (743 F.2d 1388).

(2) When sold to a purchaser also eligible for those prices under the Nonprofit Institutions Act, that controls, is controlled by, or is under common control with, the seller, and that purchases the products for its own use, as defined in paragraph (1).

(3) When sold to a walk-in customer pursuant to a prescription, provided that those sales represent less than 1 percent of the drugs purchased by the seller for its own use in this state.

(b) Nothing in this article prohibits the resale of drugs to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need.

Effective: [See Text Amendments]

§ 4381. Unfair competition; remedies; attorney fees; proof

(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.

Effective: January 01, 2001

§ 4382. Compliance audits

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.

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4383 to 4388. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4389. Repealed by Stats.1980, c. 649, p. 1822, § 21

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4390 to 4394. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2014

Article 23. Revenue and Renewal (Refs & Annos)

§ 4400. Fee and penalty schedule

<Section operative until July 1, 2014. See, also, section operative July 1, 2014.>

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 four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars ($200) and may be increased to two hundred sixty dollars ($260).

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

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars ($600), and may be increased to seven hundred eighty dollars ($780). 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). A temporary license fee shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars ($125) and may be increased to one hundred sixty-five dollars ($165).

(h)(1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars ($255) and may be increased to three hundred thirty dollars ($330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(i)(1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars ($255) and may be increased to three hundred thirty dollars ($330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(j)(1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). 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). A temporary license fee shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780).

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

(l) The fee for an intern pharmacist license shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

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

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

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

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

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars ($405) and may be increased to four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

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

(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(v) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

Effective: [See Text Amendments]

§ 4401. License renewal; fee

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.

Effective: January 01, 2000

§ 4402. Cancellation of license

(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.

Effective: January 01, 2004

§ 4403. Reissuance or renewal of license; fees

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.

Effective: January 01, 2001

§ 4404. Lost or destroyed licenses; reissuance

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.

Effective: [See Text Amendments]

§ 4405. Fines; disposition

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.

Effective: [See Text Amendments]

§ 4406. Fees collected; report; contingent fund

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.

Effective: [See Text Amendments]

§ 4407. Compensation and expenses of board members

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

Effective: January 01, 2005

§ 4409. Contributions; California Pharmacist Scholarship and Loan Repayment Program

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.

Effective: [See Text Amendments]

§ 4410. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§ 4411. Repealed by Stats.1994, c. 1275 (S.B.2101), § 35

Effective: [See Text Amendments]

§§ 4412 to 4417. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4412 to 4417. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4412 to 4417. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4412 to 4417. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4412 to 4417. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: [See Text Amendments]

§§ 4412 to 4417. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2011

Article 24. Prescription Rates for Medicare Beneficiaries (Refs & Annos)

§ 4425. Maximum charge for prescriptions; outreach program

(a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Care Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Health Care Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Health Care Services shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Health Care Services shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

Effective: January 01, 2011

§ 4426. Adequacy of reimbursement rates; study

The State Department of Health Care Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

Effective: September 30, 2002

§ 4427. Repealed by Stats.2002, c. 542 (S.B.1278), § 2; Stats.2002, c. 1161 (A.B.442), § 2, eff. Sept. 30, 2002

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

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§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4428 to 4438. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§ 4439. Repealed by Stats.1991, c. 654 (A.B.1893), § 46

Effective: January 01, 2000

§§ 4450 to 4480. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4450 to 4480. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Effective: January 01, 2000

§§ 4450 to 4480. Repealed by Stats.1996, c. 890 (A.B.2802), § 2

Current with all 2013 Reg.Sess. laws, all 2013-2014 1st Ex.Sess. laws, and Res. c. 123 (S.C.A.3)
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