

2017 LAWBOOK FOR PHARMACY

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

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

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

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

Excerpts from the Public Resources Code



Resources for Searching California Laws and Regulations:

<http://leginfo.legislature.ca.gov>
<https://govt.westlaw.com/calregs>

BUSINESS & PROFESSIONS CODE

CHAPTER 9, DIVISION 2

Article 1. Administration

Section

- 4000. Chapter Title
- 4001. Board of Pharmacy; Appointment; Terms
- 4001.1. Purpose of the Board: Protection of the Public
- 4001.5. Pharmacist Shortage; Recommendations to Alleviate
- 4002. Officers
- 4003. Executive Officer; Records; Revenue
- 4004. Teaching by Board Members
- 4005. Adoption of Rules and Regulations
- 4006. Regulations Restricting Furnishing of Particular Drug
- 4007. Limitations of Rules
- 4008. Inspectors; Authority as Public Officers
- 4009. Board Rules; Exemption from Coverage under Industrial Welfare Commission Rules
- 4010. Immunity of Officers
- 4011. Administration and Enforcement of Uniform Controlled Substances Act
- 4012. Board to Provide Copy of Laws or Regulations
- 4013. Board-Licensed Facilities to Join E-Mail Notification List

Article 2. Definitions

Section

- 4015. Definitions to Govern Construction
- 4016. Administer
- 4016.5. Advanced Practice Pharmacist
- 4017. Authorized Officers of the Law
- 4018. Board
- 4019. Chart Order
- 4021. Controlled Substance
- 4021.5. Correctional Pharmacy
- 4022. Dangerous Drug - Dangerous Device Defined
- 4022.5. Designated Representative; Designated Representative-in-Charge
- 4022.7. Designated Representative-3PL; Responsible Manager
- 4023. Device
- 4023.5. Direct Supervision and Control
- 4024. Dispense
- 4025. Drug

Section

- 4025.1. Non-Prescription Drug
- 4026. Furnish
- 4026.5 Good Standing
- 4027. Skilled Nursing Facility - Intermediate Care Facility - Other Health Care Facilities
- 4028. Licensed Hospital
- 4029. Hospital Pharmacy
- 4030. Intern Pharmacist
- 4031. Laboratory
- 4032. License
- 4033. Manufacturer
- 4034. Outsourcing Facility
- 4035. Person
- 4036. Pharmacist
- 4036.5. Pharmacist-in-Charge
- 4037. Pharmacy
- 4038. Pharmacy Technician
- 4039. Physician; Other Practitioners Defined
- 4040. Prescription; Content Requirements
- 4040.5. Reverse Distributor
- 4041. Veterinary Food-Animal Drug Retailer
- 4042. Veterinary Food-Animal Drugs
- 4043. Wholesaler
- 4044. Repackager
- 4044.5. Reverse Third-Party Logistics Provider
- 4045. Third-Party Logistics Provider
- 4045. Surplus Medication Collection and Distribution Intermediary

Article 3. Scope of Practice and Exemptions

Section

- 4050. Legislative Declaration
- 4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- 4052. Furnishing to Prescriber; Permitted Pharmacist Procedures
- 4052.01. Furnishing of Naloxone Hydrochloride; Permitted Procedures by Pharmacist
- 4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility
- 4052.2. Permitted Pharmacist Procedures in Health Care Facility, Home Health Agency or Clinic with Physician Oversight
- 4052.3. Emergency Contraception Drug Therapy; Requirements and Limitations
- 4052.4. Skin Puncture by Pharmacist
- 4052.5. Pharmacist May Select Different Form of Medication with Same Active Chemical Ingredient; Exceptions
- 4052.6. Advanced Practice Pharmacist; Permitted Procedures

Section

- 4052.7. Repackage Previously Dispensed Drug; Requirements
- 4052.8. Initiation and Administration of Vaccines; Requirements
- 4052.9. Pharmacist Furnishing Nicotine Replacement Products; Requirements
- 4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer
- 4053.1. Designated Representative-3PL to Supervise Third-Party Logistics Provider
- 4054. Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices
- 4055. Sale of Devices to Licensed Clinics, etc.
- 4056. Purchase of Drugs at Wholesale - Hospital Containing 100 Beds or Less
- 4057. Exceptions to Application of this Chapter
- 4058. Display of Original License
- 4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- 4059.5. Who May Order Dangerous Drugs or Devices: Exceptions; Compliance with Laws of All Involved Jurisdictions
- 4060. Controlled Substance - Prescription Required; Exceptions
- 4061. Distribution of Drug as Sample; Written Request Required
- 4062. Furnishing Dangerous Drugs during Emergency
- 4063. Refill of Prescription for Dangerous Drug or Device Requires Prescriber Authorization
- 4064. Emergency Refill of Prescription without Prescriber Authorization
- 4064.5. Dispensing a 90-Day Supply of a Dangerous Drug or Device; Requirements and Exceptions
- 4065. Injection Card System; Requirements for Administration
- 4066. Furnishing Dangerous Drugs to Master or First Officer of Vessel
- 4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription
- 4068. Dispense Dangerous Drugs or Controlled Substances to Emergency Room Patient; Requirements

Article 4. Requirements for Prescriptions

Section

- 4070. Reduction of Oral or Electronic Prescription to Writing
- 4071. Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded
- 4071.1. Electronic Prescription Entry into Pharmacy or Hospital Computer
- 4072. Oral or Electronic Transmission of Prescription - Health Care Facility
- 4073. Substitution of Generic Drug - Requirements and Exceptions
- 4073.5. Substitution of Alternative Biological Product; Requirements and Exceptions
- 4074. Drug Risk: Informing Patient; Providing Consultation for Discharge Medications

Section

- 4075. Proof of Identity Required - Oral or Electronic Prescription
- 4076. Prescription Container - Requirements for Labeling
- 4076.5 Standardized, Patient-Centered Prescription Labels; Requirements
- 4076.6 Patient-Centered Prescription Labels; Translated Directions for Use; Requirements
- 4077. Dispensing Dangerous Drug in Incorrectly Labeled Container
- 4078. False or Misleading Label on Prescription

Article 5. Authority of Inspectors**Section**

- 4080. Stock of Dangerous Drugs and Devices Kept Open for Inspection
- 4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- 4082. Names of Owners, Managers and Employees Open for Inspection
- 4083. Orders of Correction
- 4084. Adulterated, Misbranded or Counterfeit Dangerous Drug or Device
- 4085. Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device
- 4086. Adulterated or Counterfeit Dangerous Drug or Dangerous Device; Court Proceedings

Article 6. General Requirements**Section**

- 4100. Change of Address or Name - Notification to Board
- 4101. Pharmacist-in-Charge, Designated Representative-in-Charge: Termination of Employment; Notification to Board
- 4103. Blood Pressure - Taking by Pharmacist
- 4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures
- 4105. Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records
- 4105.5 Automated Drug Delivery Systems; Requirements
- 4106. License Verification Using Board Web Site
- 4107. One Site License per Premises; Exception
- 4107.5. Counterfeit Dangerous Drugs or Device; Fraudulent Transaction; Required Notice to the Board

Article 7. Pharmacies

Section

- 4110. License Required; Temporary Permit upon Transfer of Ownership; Temporary Use of Mobile Pharmacy
- 4111. Restrictions on Prescriber Ownership
- 4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
- 4113. Pharmacist in Charge: Notification to Board; Responsibilities
- 4114. Intern Pharmacist: Activities Permitted
- 4115. Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios
- 4115.5 Pharmacy Technician Trainee; Placement; Supervision; Requirements
- 4116. Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations
- 4117. Admission to Area Where Narcotics are Stored, etc. - Who May Enter
- 4118. Waiving of Minimum Requirements by Board
- 4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
- 4119.1 Pharmacy May Provide Services to Health Facility
- 4119.2. Furnish Epinephrine Auto-Injectors to School; Requirements
- 4119.3. Furnish Epinephrine Auto-Injectors to First Responder or Lay Rescuer; Requirements
- 4119.5. Transfer or Repackaging Dangerous Drugs by Pharmacy
- 4119.6. Health Care Facility; Stocking of Emergency Pharmaceutical Supplies Container and Emergency medical System Supplies
- 4119.7. Health Care Facility; Inspection of Drugs; Furnishing Per Standing Orders, etc.
- 4119.8 Naloxone Hydrochloride Furnished to School District, County Office of Education or Charter School; Records Requirements
- 4120. Nonresident Pharmacy: Registration Required
- 4121. Advertisement for Prescription Drug: Requirements; Restrictions
- 4122. Required Notice of Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
- 4123. Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
- 4124. Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies
- 4125. Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents
- 4126. Covered Entity May Contract with Pharmacy to Provide Pharmacy Services; Segregation of Drug Stock; Return of Drugs not Dispensed; Wholesale License Not Permitted or Required
- 4126.5 Furnishing Dangerous Drug by Pharmacy

Section

4126.9 Recall of Nonsterile Compounded Drugs: Requirements

Article 7.5. Compounded Sterile Drug Products**Section**

4127. Board Shall Adopt Regulations Establishing Standards

4127.1 License to Compound Injectable Sterile Drug Products Required

4127.2 Nonresident Pharmacy – License to Compound and Ship Injectable Drug Products into California Required

4127.3 Cease and Desist Order; Hearing

4127.4 Fine for Violation

4127.6 Article Operative upon Allocation of Positions

4127.7 Compounding Sterile Injectable from Nonsterile Ingredients; Requirements

4127.8 Temporary License to Compound Injectable Sterile Drug Products When a Change of Ownership

4127.9 Pharmacies that Compound Sterile Drug Products; Recalls; Requirements

Article 7.6. Centralized Hospital Packaging Pharmacy**Section**

4128. Centralized Hospital Packaging

4128.2. Specialty License Required; Application; Fees

4128.3. Preparing and Storing Limited Quantity of Unit Dose Drugs in Advance of a Patient-Specific Prescription

4128.4. Barcode Required; Information Retrievable Upon Reading Barcode

4128.5. Labeling for Unit Dose Medications

4128.6. Compounding

4128.7. Integrity, Potency, Quality and Labeled Strength of Unit Dose Drug Products

Article 7.7. Outsourcing Facilities**Section**

4129 Outsourcing Facility; License Required

4129.1 Licensing Requirements

4129.2 Nonresident Outsourcing Facility; License Required

4129.3 Board Report to the Legislature

4129.4 Cease and Desist Order

4129.5 Violation Fine

4129.8 Temporary License

4129.9 Recall: Notice Required

Article 9. Hypodermic Needles and Syringes

Section

- 4141. Furnishing without License
- 4142. Prescription Required
- 4143. Exemption: Sale to Other Entity, Physician, etc.
- 4144.5. Industrial Use; Exception
- 4145.5. Conditions for Furnishing Hypodermic Needles and Syringes for Human Use or Specified Animal Use without a Prescription
- 4146. Needle/Syringe Return in Sharps Container
- 4147. Disposal of Needle or Syringe
- 4148.5. Confiscation if Found Outside Licensed Premises
- 4149. Sale by Nonresident Distributor; License Required

Article 10. Pharmacy Corporations

Section

- 4150. Definitions
- 4151. Licensure Requirements
- 4152. Corporate Name Requirements
- 4153. Shareholder Income While Disqualified
- 4154. Regulations Authorized
- 4155. Corporate Form Not Required
- 4156. Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

Section

- 4160. Wholesaler: License Required
- 4161. Nonresident Wholesaler Requirements
- 4161.5. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider
- 4162. Wholesaler or Third-Party Logistics Provider; Surety Bond Requirements
- 4162.5. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Surety Bond Requirements
- 4163. Unauthorized Furnishing by Manufacturer or Wholesaler
- 4164. Reports Required
- 4165. Sale or Transfer of Dangerous Drug or Device into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
- 4166. Shipping of Dangerous Drugs or Devices - Wholesaler or Distributor Liable for Security and Integrity until Delivery
- 4167. Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises
- 4168. Board License Required for Local Business License

Section

4169. Prohibited Acts

Article 11.5. Surplus Medication Collection and Distribution Intermediaries**Section**

4169.5 Surplus Medication Collection and Distribution Intermediary; License Required

Article 12. Prescriber Dispensing**Section**

- 4170. Dispensing by Prescriber: Requirements and Restrictions; Enforcement
- 4170.5 Veterinarian in Teaching Hospital May Dispense and Administer Dangerous Drugs and Devices; Requirements
- 4171. Exceptions to Section 4170: Samples; Clinics; Veterinarians; Narcotic Treatment Programs; Certain Cancer Medications
- 4172. Storage Requirements
- 4173. Dispensing by Registered Nurses
- 4174. Dispensing by Pharmacist upon Order of Nurse Practitioner
- 4175. Processing of Complaints

Article 13. Nonprofit or Free Clinics**Section**

- 4180. Purchase of Drugs at Wholesale Only with License: Eligible Clinics
- 4181. License Requirements; Policies and Procedures; Who May Dispense
- 4182. Duties of Professional Director; Consulting Pharmacist Required
- 4183. No Professional Dispensing Fee
- 4184. Dispensing Schedule II Substance by Clinic is Prohibited
- 4185. Inspection Permitted
- 4186. Automated Drug Delivery Systems

Article 14. Clinics**Section**

- 4190. Clinic Defined; License Required; Purchase of Drugs at Wholesale: Drug Distribution Service of a Clinic; Information Reported to the Board
- 4191. Compliance with Department of Health Services Requirements; Who May Dispense Drugs

Section

- 4192. Duties of Professional Director; Providing Information to Board
- 4193. Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale
- 4194. Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic
- 4195. Inspection Authorized

Article 15. Veterinary Food-Animal Drug Retailers**Section**

- 4196. License Required: Temporary License on Transfer of Ownership; Board Approval of Designated Representative-in-Charge
- 4197. Minimum Standards: Security; Sanitation; Board Regulations; Waivers
- 4198. Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist
- 4199. Labeling Requirements; Maintaining Prescription Records

Article 16. Applications**Section**

- 4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees
- 4200.1. Multiple Failures of License Examination: Additional Education Requirement
- 4200.2. California Practice Standards and Jurisprudence Examination for Pharmacist; Required Inclusions
- 4200.3. Examination Process to be Reviewed Regularly; Required Standards
- 4200.4. Retaking National Examination after Failure; Waiting Period
- 4200.5. Retired Licensee: Eligibility; Bar on Practice; Requirement for Restoration to Active Status
- 4201. Application Form: Required Information; Authority Granted by License; Reporting Changes in Beneficial Ownership
- 4202. Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline
- 4203. Non-Profit Clinic License Application: Form; Investigation
- 4203.5. Clinic Application
- 4204. Surgical Clinic Application: Form; Investigation
- 4205. Sale or Dispensing of Hypodermic Syringes and Needles: When Separate License Required; Form and Content of Application; Renewability; Discipline
- 4207. Investigation by Board
- 4208. Intern Pharmacist License

Section

- 4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam
- 4210. Advanced Practice Pharmacist License

Article 17. Continuing Education**Section**

- 4231. Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
- 4232. Content of Courses
- 4233. Advanced Practice Pharmacist; Continuing Education Requirements
- 4234. Exceptions: Emergencies; Hardship

Article 18. Poisons**Section**

- 4240. California Hazardous Substances Act; Application of Act

Article 19. Disciplinary Proceedings**Section**

- 4300. Revocation and Suspension: Authority; Conditions; Issuance of Probationary License; Application of Administrative Procedure Act; Judicial Review
- 4300.1. Board Authority to Render a Decision on a License
- 4301. Obtaining License by Fraud or Misrepresentation; Unprofessional Conduct
- 4301.1. Investigative Priority: Greatest Threat of Patient Harm
- 4301.5. Pharmacist License; Out-of-State Suspension or Revocation to Apply to California License
- 4302. Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
- 4303. Nonresident Pharmacy: Grounds for Discipline
- 4303.1. Outsourcing Facility: License Canceled, Revoked or Suspended by Operation of Law
- 4304. Nonresident Wholesaler: Authority to Discipline
- 4305. Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist-in-Charge; Continuing to Operate Without Pharmacist

Section

- 4305.5. Disciplinary Grounds: Failure of Wholesaler, Veterinary Food-Animal Drug Retailer or Third-Party Logistics Provider to Notify Board of Termination of Designated Representative-in-Charge or Responsible Manager; Continuing to Operate Without a Designated Representative-in-Charge or Responsible Manager
- 4306. Violation of Professional Corporation Act as Unprofessional Conduct
- 4306.5. Acts or Omissions by Pharmacist: Unprofessional Conduct
- 4306.6 Mitigating Factors for Pharmacist-in-Charge Reporting Violations of Others
- 4307. Individuals with Denied, Revoked, Suspended, etc., Licenses Prohibited from Pharmacy Ownership or Association with Board Licensed Entities
- 4308. Prohibited Association: Notification of Affected Licensees Known to Board
- 4309. Petition for Reinstatement, etc. of Disciplined License: Time for Filing; Contents; Investigation; Hearing; Factors to Be Considered; Effect of Ongoing Criminal Sentence or Accusation or Petition to Revoke Probation
- 4310. Notice of Denial of Application: Petition for Licensure; Application of Administrative Procedure Act
- 4311. Suspension of License for Felony Conviction: Automatic Suspension; Summary Suspension; Other Suspensions; Applicable Proceedings
- 4312. Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock
- 4313. Evidence of Rehabilitation; Priority of Public Protection
- 4314. Orders of Abatement
- 4315. Letters of Admonishment
- 4316. Cease and Desist Orders

Article 20. Prohibitions and Offenses**Section**

- 4320. Penalties for Violation of Pharmacy Law: Actions Authorized; Who May File Actions
- 4321. Penalties: Misdemeanors; Infractions
- 4322. Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
- 4323. Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
- 4324. Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
- 4325. Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
- 4326. Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another

Section

- 4327. Misdemeanor: Sale, Dispensing, or Compounding While under the Influence of Drugs or Alcoholic Beverages
- 4328. Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-Pharmacist
- 4329. Misdemeanor: Non-Pharmacist Acting as Manager; Compounding, Dispensing or Furnishing Drugs
- 4330. Misdemeanor: Non-Pharmacist Owner Failing to Place Pharmacist-in-Charge; Dispensing or Compounding Except by Pharmacist; Interfering with Pharmacist-in-Charge
- 4331. Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Designated Representative-in-Charge; Permitting Dispensing or Compounding Except by Pharmacist or Designated Representative
- 4332. Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records
- 4333. Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records is Misdemeanor
- 4335. Knowingly Failing to Arrange for Disposition of Stock of Closed or Discontinued Business: Misdemeanor
- 4336. Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription
- 4337. Distribution of Fines Collected
- 4338. Additional Fines May be Assessed
- 4339. Board Action to Enjoin Violation of Pharmacy Law; Exception for Certain Drugs and Devices
- 4340. Unlawful Advertising by Nonresident Pharmacy Not Registered with Board
- 4341. Advertisement of Prescription Drugs or Devices
- 4342. Actions by Board to Prevent Sales of Preparations or Drugs Lacking Quality or Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales
- 4343. Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

Article 21. Pharmacists Recovery Program**Section**

- 4360. Impaired Pharmacists: Legislative Intent
- 4361. Definitions
- 4362. Function of Program: Board Referrals; Voluntary, Confidential Participation
- 4364. Criteria for Participation to Be Established by Board
- 4365. Contracting with Employee Assistance Program: Selection

Section

- 4366. Function of the Employee Assistance Program
- 4369. Board Referrals to Program: Written Information Provided to Licensee; Termination for Non-Compliance; Report to Board of Termination When Public Safety Threatened; Authority to Discipline
- 4371. Review of Activities of Program
- 4372. Confidential Records; Exception for Disciplinary Proceeding
- 4373. Immunity from Civil Liability

Article 22. Unfair Trade Practices**Section**

- 4380. Resale of Preferentially Priced Drugs: Prohibition; Exceptions
- 4381. Violation of Article as Unfair Competition; Private Actions Authorized; Triple Damages and Attorneys' Fees; Proof Required
- 4382. Board May Audit Sales to Walk-in Customers

Article 23. Revenue and Renewal**Section**

- 4400. Fees
- 4401. Pharmacist: Biennial Renewal
- 4402. Cancellation: of Pharmacist after Non-Renewal for Three Years; All Other Licenses after 60 Days
- 4403. Reissuance without Payment of Fees Prohibited
- 4404. Reissuance of Lost or Destroyed License; Proof of Loss, etc.
- 4405. Disposition of Fines
- 4406. Report of Fees Collected
- 4407. Compensation of Members
- 4409. Pharmacist Scholarship Program, Donations

Article 24. Prescription Rates for Medicare Beneficiaries**Section**

- 4425. Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
- 4426. Department of Health Services to Study Reimbursement Rates

Other Important Sections of the Business & Professions Code**Section**

- 31 Licensee or Applicant Name on Tax Delinquencies List
- 40 Expert Consultant Agreement
- 114.5. Applicants; Military Service Inquiry
- 115.4. Expedited Licensure For Honorably Discharged Member of the Armed Forces

Section

- 115.5. Expedited Licensure Process
- 125.3. Recovery of Investigation and Enforcement Costs: Procedures; Proof; Enforcement
- 125.9. Citation and Fine
- 144.5. Authority to Receive Certified Records
- 148. Unlicensed Activity
- 208. CURES Fee Assessment
- 209. CURES Prescription Drug Monitoring Program; Application and Approval Process
- 315.2 Violation of Probation; Order for Licensee to Cease Practice
- 315.4 Order Clinical Diagnostic Evaluation for Licensee
- 460 Licensed Department of Consumer Affairs Businesses
- 476 Licensure/Registration Related to Section 31
- 480 Denial of Licenses
- 494.5. License Shall Not be Issued, Reactivated, Reinstated, or Renewed and be Suspended if Named on Certified Tax Delinquencies List
- 650. Rebates or Discounts for Referral Prohibited
- 650.1. Lease Prohibition - Hospitals or Prescribers
- 651. Professional Advertising Requirements
- 652. Violation as Unprofessional Conduct
- 652.5. Violation as Misdemeanor
- 733. Dispensing Prescription Drugs and Devices
- 901. Authorization for Out-of-State Health Practitioners to Participate in Sponsored Events in California
- 17500. False or Misleading Statements, Generally

BUSINESS & PROFESSIONS CODE

CHAPTER 9, DIVISION 2

Article 1. Administration

4000. Chapter Title

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

4001. Board of Pharmacy; Appointment; Terms

(a) There is in the Department of Consumer Affairs 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, 2021, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

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

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

4001.5. Pharmacist Shortage; Recommendations to Alleviate

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.

4002. Officers

(a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.

(b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Seven members of the board constitute a quorum.

4003. Executive Officer; Records; Revenue

(a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in 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, 2021, and as of that date is repealed.

4004. Teaching by Board Members

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

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

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

4005. Adoption of Rules and Regulations

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

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

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

4006. Regulations Restricting Furnishing of Particular Drug

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

4007. Limitations of Rules

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

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

4008. Inspectors; Authority as Public Officers

(a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board

or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

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

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

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

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

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

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

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

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

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

4010. Immunity of Officers

All authorized officers of the law, while investigating violations of this chapter in performance of their official duties, and any person working under

their immediate direction, supervision, or instruction are immune from prosecution under this chapter.

4011. Administration and Enforcement of Uniform Controlled Substances Act

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

4012. Board to Provide Copy of Laws or Regulations

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

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

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

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

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

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

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

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

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

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

Article 2. Definitions

4015. Definitions to Govern Construction

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

4016. Administer

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

4016.5. Advanced Practice Pharmacist

"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.

4017. Authorized Officers of the Law

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

4018. Board

"Board" means the California State Board of Pharmacy.

4019. Chart Order An "order," entered on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by law to prescribe drugs, shall be authorization for the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted under Section 4056, and shall be considered to be a prescription if the medication is to be furnished directly to the patient by the hospital pharmacy or another pharmacy furnishing prescribed drugs for hospital patients; provided that the chart or medical record of the patient contains all of the information required by Sections 4040 and 4070 and the order is signed by the practitioner authorized by law to prescribe drugs, if he or she is present when the drugs are given. If he or she is not present when the drugs are given, the order shall be signed either by the attending physician responsible for the patient's care at the time the drugs are given to the patient or by the practitioner who ordered the drugs for the patient on the practitioner's next visit to the hospital.

4021. Controlled Substance

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

4021.5. Correctional Pharmacy

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

4022. Dangerous Drug – Dangerous Device Defined

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

- (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

4022.5. Designated Representative; Designated Representative-in-Charge

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

(b) "Designated representative-in-charge" means a designated representative or 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.

4022.7. Designated Representative-3PL; Responsible Manager

(a) "Designated representative-3PL" means an individual to whom a license has been granted pursuant to Section 4053.1.

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

4023. Device

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

- (a) Use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or any other animal.
- (b) To affect the structure or any function of the body of a human or any other animal.

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

4023.5. Direct Supervision and Control

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

4024. Dispense

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

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

4025. Drug

"Drug" means any of the following:

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

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

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

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

4025.1. Non-Prescription Drug

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

4026. Furnish

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

4026.5. Good Standing

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

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

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

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

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

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

4028. Licensed Hospital

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

4029. Hospital Pharmacy

(a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight

stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy 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.

4030. Intern Pharmacist

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

4031. Laboratory

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

4032. License

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

4033. Manufacturer

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

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

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

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the

holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

4034. Outsourcing Facility

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

- (a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.
- (b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).
- (c) Is doing business within or into California.
- (d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).

4035. Person

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

4036. Pharmacist

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

4036.5. Pharmacist-in-Charge

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

4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of 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.

4038. Pharmacy Technician

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

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

4039. Physician; Other Practitioners Defined

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

4040. Prescription; Content Requirements

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

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

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

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

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, 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.

4040.5. Reverse Distributor

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

4041. Veterinary Food-Animal Drug Retailer

"Veterinary food-animal drug retailer" is an area, place, or premises, other than a pharmacy, that holds a valid license from the Board of Pharmacy of the State of California as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed veterinarian. "Veterinary food-animal retailer" includes, but is not limited to, any area, place, or premises described in a permit issued by the board wherein veterinary food-animal drugs, as defined in Section 4042, are stored, possessed, or repackaged, and from which veterinary drugs are

furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

4042. Veterinary Food-Animal Drugs

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

- (a) Any drug to be used in food-producing animals bearing the legend, "Caution, federal law restricts this drug to use by or on the order of a licensed veterinarian" or words of similar import.
- (b) Any other drug as defined in Section 14206 of the Food and Agricultural Code that is used in a manner that would require a veterinary prescription.

4043. Wholesaler

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

4044. Repackager

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

4044.5. Reverse Third-Party Logistics Provider

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

4045. Third-Party Logistics Provider

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

4046. Surplus Medication Collection and Distribution Intermediary

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

Article 3. Scope of Practice and Exemptions

4050. Legislative Declaration

(a) 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.

4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

(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.

4052. Furnishing to Prescriber; Permitted Procedures by Pharmacist

(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.

4052.01. Furnishing of Naloxone Hydrochloride; Permitted Procedures by Pharmacist

(a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:

(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.

(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.

(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.

(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.

(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.

(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.

(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility

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

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

(2) Ordering drug therapy-related laboratory tests.

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

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

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

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

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

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

(2) Ordering drug therapy-related laboratory tests.

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

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

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

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

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

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

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

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

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

(1) Successfully completed clinical residency training.

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

4052.3. Emergency Contraception Drug Therapy; Requirements and Limitations

(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.

4052.4. Skin Puncture by Pharmacist; Conditions Permitting

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.

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

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

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

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

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

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

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

name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.

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

4052.6. Advanced Practice Pharmacist; Permitted Procedures

(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.

4052.7. Repackage Previously Dispensed Drug; Requirements

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.

(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:

- (1) All the information required by Section 4076.
- (2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

4052.8. Initiation and Administration of Vaccines; Requirements

(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.

4052.9. Pharmacist Furnishing Nicotine Replacement Products; Requirements

(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.

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

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

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

(1) 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).

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

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

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

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

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

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

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

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

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

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

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

(iii) Knowledge and understanding of quality control systems.

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

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

(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.

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

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

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

4055. Sale of Devices to Licensed Clinics, etc.

Nothing in this chapter, nor any other law, shall prohibit the sale of devices to clinics that have been issued a clinic license pursuant to Article 13 (commencing with Section 4180) of this chapter, or to skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of, or to home health agencies licensed pursuant to Chapter 8 (commencing with Section 1725) of, or to hospices licensed pursuant to Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, as long as the devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

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

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

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

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

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

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

(f) A physician himself or herself may dispense drugs to outpatients directly pursuant to subdivision (a) only if the physician determines that it is in the best

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

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

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

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

4057. Exceptions to Application of this Chapter

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

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

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

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

(c) This chapter shall not apply to a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, when it purchases, stores, furnishes, or transports specific

dangerous drugs and dangerous devices listed in board regulations in compliance with applicable law and regulations including:

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

(2) Hypodermic needles and syringes.

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

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

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

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

4058. Display of Original License

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

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

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

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

the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

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

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

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

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

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

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

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

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

4060. Controlled Substance: Prescription Required; Exceptions

A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, 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, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer.

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

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

(a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to a protocol described in Section 3502.1, or a naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725, 3502.1, or 3640.5, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, physician assistant, or naturopathic doctor, shall be defined within the standardized procedure, protocol, or practice agreement.

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

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

4062. Furnishing Dangerous Drugs during Emergency; 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.

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

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given

orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

4064. Emergency Refill of Prescription without Prescriber Authorization

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

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

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

(d) 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.

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

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

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

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

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

(4) The pharmacist is exercising 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) Except for the provisions of subdivision (d), this section does not apply to FDA-approved, self-administered hormonal contraceptives.

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

(2) A pharmacist furnishing an FDA-approved, self-administered hormonal contraceptive pursuant to Section 4052.3 under protocols developed by the Board of Pharmacy may furnish, at the patient's request, up to a 12-month supply at one time.

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

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

4065. Injection Card System; Requirements for Administration

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

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

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

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

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

- (1) Identification of drugs to be included in the injection card system.
 - (2) Distinction among classes of drugs.
 - (3) Periodic review of the efficacy of the injection card system, including, but not limited to, its effectiveness and safety for different classes of drugs.
 - (4) Determination as to whether each drug included in the injection card system requires the presence of a physician or only the ready availability of a physician.
 - (5) Implementation of recordkeeping systems that, at a minimum, record each injection and each visit, provide for the immediate entry of the injection in the patient's medical record, provide a system for discontinuance of the order by the prescribing physician, and allow for ready identification of patterns of possible or actual patient abuse of controlled substances and other potential adverse drug interactions.
 - (6) Retention of the injection card by the facility at all times when a controlled substance is being administered.
 - (7) Adequate initial evaluation of patients, including, but not limited to, a determination as to whether each patient is a proper subject for the injection card system.
 - (8) Ongoing medical evaluation of the patient's response to the injection card system.
 - (9) That all injection cards shall become a permanent part of the patient's medical record within 15 days from the date the last authorized dose is administered.
- (d) Nothing in this section shall be construed to prohibit the use, or impose new requirements on the use, of an injection card system for noncontrolled substances.

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

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

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

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

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

4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription

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

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

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

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

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

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

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

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

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

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

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

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

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

(6) The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.

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

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

Article 4. Requirements for Prescriptions

4070. Reduction of Oral or Electronic Prescription to Writing

(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

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

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the

information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

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

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

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

4071.1. Electronic Prescription Entry into Pharmacy or Hospital Computer

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

(b) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

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

(a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other

health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

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

4073. Substitution of Generic Drug —Requirements and Exceptions

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

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

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

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

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

4073.5. Substitution of Alternative Biological Product; Requirements and Exceptions

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

- (1) The alternative biological product is interchangeable.
- (2) The prescriber does not personally indicate “Do not substitute,” or words of similar meaning, in the manner provided in subdivision (d).

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

- (1) An interoperable electronic medical records system.
- (2) An electronic prescribing technology.
- (3) A pharmacy benefit management system.
- (4) A pharmacy record.

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

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist’s designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

- (1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.
- (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4075. Proof of Identity Required – Oral or Electronic Prescription

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

4076. Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense 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.

(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

(Amended by Stats. 2015, Ch. 784, Sec. 1. Effective January 1, 2016.)

4076.5. Standardized, Patient-Centered Prescription Labels; Requirements

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

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

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

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

(2) Improved directions for use.

(3) Improved font types and sizes.

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

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

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be

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

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

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

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

(C) The patient receives weekly or more frequent 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.

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

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

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

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

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

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a

dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076.

(f) For purposes of this section, a dispenser does not include a veterinarian. *(Added by Stats. 2015, Ch. 784, Sec. 2. Effective January 1, 2016.)*

4077. Dispensing Dangerous Drug in Incorrectly Labeled Container

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

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

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

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

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

4078. False or Misleading Label on Prescription

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

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

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

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

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

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

Article 5. Authority of Inspectors

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

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

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

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

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

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

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

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

4083. Orders of Correction

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

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

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

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

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

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

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

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

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

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

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

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

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

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

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

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

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

4084. Adulterated, Misbranded or Counterfeit Dangerous Drug or Device

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

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

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

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

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

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

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

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

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

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

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

(b) If the court finds that an embargoed dangerous drug or dangerous device is adulterated or counterfeit, the dangerous drug or dangerous device shall, after

entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of the board. All court costs and fees and all reasonable costs incurred by the board in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be paid by the claimant or owner of the dangerous drug or dangerous device.

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

Article 6. General Requirements

4100. Change of Address or Name – Notification to Board

(a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, or designated representative shall notify the executive officer of the board of the change of address or change of name.

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

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

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

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

(c) A designated representative-3PL may take charge of, and act as, the responsible manager of a third-party logistics provider upon application by the third-party logistics provider and approval by the board. A responsible manager who ceases to act as the responsible manager at that entity shall notify the board in writing within 30 days of the date of that change in status.

4103. Blood Pressure—Taking by Pharmacist

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

4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures

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

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

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

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

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

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

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

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

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

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

(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from

the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

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

(a) All records or other documentation 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) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

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

4105.5. Automated Drug Delivery System; Requirements

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

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

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

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

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

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

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

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

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

4106. License Verification Using Board Web Site

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

4107. One Site License per Premises; Exception

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

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

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

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

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

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

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

Article 7. Pharmacies

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

(a) No person shall conduct a pharmacy in the State of California unless 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 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.

4111. Restrictions on Prescriber Ownership

- (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.

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

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

(b) A person may not act as a nonresident pharmacy unless 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.

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

(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.

4114. Intern Pharmacist: Activities Permitted

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

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

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

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

(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.

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

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

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

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

4115.5. Pharmacy Technician Trainee; Placement; Supervision; Requirements

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

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

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

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

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

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

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

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.

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

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

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

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the

pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

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

(2) The board shall, by regulation, establish conditions for the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing authorized personnel from the pharmacy. These conditions shall ensure the security of the pharmacy and its operations during the temporary absence of the pharmacist and shall allow, at the discretion of the pharmacist, nonpharmacist personnel to remain and perform any lawful activities during the pharmacist's temporary absence.

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

No person other than a pharmacist, an intern pharmacist, a pharmacy technician, an authorized officer of the law, a person authorized to prescribe, a registered nurse, a licensed vocational nurse, a person who enters the pharmacy for purposes of receiving consultation from a pharmacist, or a person authorized by the pharmacist in charge to perform clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy shall be permitted in that area, place, or premises described in the license issued by the board to a licensed hospital wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.

4118. Waiving of Minimum Requirements by Board

(a) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements.

(b) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a hospital pharmacy, as defined by subdivision (a) of Section 4029, that does not meet all of the requirements for licensure as a hospital pharmacy, the board may waive any licensing requirements. However, when a waiver of any requirements is granted by the board, the pharmaceutical services to be rendered by this pharmacy shall be limited to patients registered for treatment in the hospital, whether or not they are actually staying in the hospital, or to emergency cases under treatment in the hospital.

4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

(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.

4119.1. Pharmacy May Provide Services to Health 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) This section shall not be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

4119.2. Furnish Epinephrine Auto-Injectors to School; Requirements

(a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to a school district, county office of education, or charter school 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, county office of education, or charter school.

(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 the school district, county office of education, or charter school for a period of three years from the date the records were created. The school district, county office of education, or charter school shall be responsible for monitoring the supply of epinephrine auto-injectors and ensuring the destruction of expired epinephrine auto-injectors.

4119.3. Furnish Epinephrine Auto-Injectors to First Responder or Lay Rescuer; Requirements

(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.

4119.4. Epinephrine Auto-injector; Labeling; Records Requirements

(a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to an authorized entity, for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

(1) The epinephrine auto-injectors are furnished exclusively for use by, or in connection with, an authorized entity.

(2) An authorized health care provider provides a prescription that specifies the quantity of epinephrine auto-injectors to be furnished to an authorized entity described in subdivision (a) of Section 1797.197a of the Health and Safety Code. A new prescription shall be written for any additional epinephrine auto-injectors required for use.

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

(1) The name of the person or entity to whom the prescription was issued.

(2) The designations “Section 1797.197a Responder” and “First Aid Purposes Only.”

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

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

(d) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by the authorized entity for a period of three years from the date the records were created. The authorized entity shall be responsible for monitoring the supply of epinephrine auto-injectors and ensuring the destruction of expired epinephrine auto-injectors.

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

(f) For purposes of this section, "epinephrine auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.

4119.5. Transfer or Repackaging Dangerous Drugs by Pharmacy

(a) A pharmacy can transfer a reasonable supply of dangerous drugs to another pharmacy.

(b) A pharmacy may repackage and furnish to a prescriber a reasonable quantity of dangerous drugs and dangerous devices for prescriber office use.

4119.6. Health Care Facility; Stocking of Emergency Pharmaceutical Supplies Container and Emergency Medical System Supplies

An intern pharmacist under the direct supervision and control, as defined in Section 4023.5, of a pharmacist may stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code.

4119.7. Health Care Facility; Inspection of Drugs; Furnishing Per Standing Orders, etc.

(a) Notwithstanding any other law, a hospital pharmacy serving a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code may furnish a dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocols established under the policies and procedures of the health care facility, as approved according to the policies of the health care facility's governing body, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device will be provided.

(b) A health care facility shall store and maintain drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. The health care facility's policies and procedures shall specify these storage parameters.

(c) An intern pharmacist under the direct supervision and control, as defined in Section 4023.5, of a pharmacist, may inspect the drugs maintained in the health

care facility at least once per month. The health care facility shall establish specific written policies and procedures for inspections pursuant to this subdivision.

(d) For purposes of this section, “health care facility” means a health facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code.

4119.8. Naloxone Hydrochloride Furnished to School District, County Office of Education or Charter School; Records Requirements

(a) Notwithstanding any other law, a pharmacy may furnish naloxone hydrochloride or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code if all of the following are met:

(1) The naloxone hydrochloride or another opioid antagonist is furnished exclusively for use at a school district schoolsite, county office of education schoolsite, or charter school.

(2) A physician and surgeon provides a written order that specifies the quantity of naloxone hydrochloride or another opioid antagonist to be furnished.

(b) Records regarding the acquisition and disposition of naloxone hydrochloride or another opioid antagonist furnished pursuant to subdivision (a) shall be maintained by the school district, county office of education, or charter school for a period of three years from the date the records were created. The school district, county office of education, or charter school shall be responsible for monitoring the supply of naloxone hydrochloride or another opioid antagonist and ensuring the destruction of expired naloxone hydrochloride or another opioid antagonist.

4120. Nonresident Pharmacy: Registration Required

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler or third-party logistics provider who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler or third-party logistics provider pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

4121. Advertisement for Prescription Drug: Requirements; Restrictions

(a) Notwithstanding Section 651, an advertisement of the retail price for a drug that requires a prescription shall be limited to quantities of the drug that are consistent with good medical practice and shall include the strength, dosage form, and the exact dates during which the advertised price will be in effect.

(b) This section shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

4122. Required Notice of Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Price Information; Limitations on Price Information Requests

(a) In every pharmacy there shall be prominently posted in a place conspicuous to, and readable by, prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, the type of services provided by pharmacies, and a statement describing patients' rights relative to the requirements imposed on pharmacists pursuant to Section 733. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

4123. Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

4124. Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

(a) Notwithstanding Section 2543, a pharmacist may dispense replacement contact lenses pursuant to a valid prescription of a physician or optometrist. Nothing in this section authorizes a pharmacist to conduct an examination of the eyes or to fit or adjust contact lenses. For purposes of this section, "replacement contact lenses" means soft contact lenses that require no fitting or adjustment, and that are dispensed as packaged and sealed by the manufacturer.

(b) No replacement contact lenses may be sold or dispensed except pursuant to a prescription that meets all of the following requirements:

(1) Conforms to state and federal statutes and regulations governing those prescriptions and includes the name, address, and state license number of the prescribing practitioner.

(2) Explicitly states an expiration date of not more than one year from the date of the last prescribing examination.

(3) Explicitly states that the prescription is for contact lenses and includes the lens brand name, type, and tint, including all specifications necessary for the ordering of lenses.

(c) The contact lenses that are dispensed shall be the exact contact lenses that have been prescribed, and no substitutions shall be made.

(d) Any pharmacist and pharmacy that dispenses replacement contact lenses shall direct the patient to confer with his or her eyecare practitioner in the event of any eye problem or reaction to the lenses.

(e) Any pharmacist and pharmacy that sells replacement contact lenses shall provide the following or substantially equivalent written notification to the patient whenever contact lenses are supplied:

WARNING: IF YOU ARE HAVING ANY UNEXPLAINED EYE DISCOMFORT, WATERING, VISION CHANGE, OR REDNESS, REMOVE YOUR LENSES IMMEDIATELY AND CONSULT YOUR EYE CARE PRACTITIONER BEFORE WEARING YOUR LENSES AGAIN.

(f) Any pharmacy and pharmacist dispensing replacement contact lenses shall be subject to all statutes, regulations, and ordinances governing the advertisement of contact lenses. In addition, any advertisement by a pharmacy or pharmacist that mentions replacement contact lenses shall include within the advertisement all fees, charges, and costs associated with the purchase of the lenses from that pharmacy and pharmacist.

(g) Any pharmacy dispensing replacement contact lenses shall register with the Medical Board of California at the time of initial application for a license or at the time of annual renewal of that license.

(h) All nonresident pharmacies shall maintain records of replacement contact lenses shipped, mailed, or delivered to persons in California for a period of at least three years. The records shall be available for inspection upon request by the board or the Division of Licensing of the Medical Board of California.

(i) The requirements of this section are applicable to nonresident pharmacies as defined in subdivision (a) of Section 4112. A nonresident pharmacy may dispense contact lenses only as provided in this section.

4125. Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

4126. Covered Entity May Contract With Pharmacy to Provide Pharmacy Services; Segregation of Drug Stock; Return of Drugs Not Dispensed; Wholesale License Not Permitted or Required

(a) Notwithstanding any other provision of law, a covered entity may contract with a pharmacy to provide pharmacy services to patients of the covered entity, as defined in Section 256b of Title 42 of the United States Code, including dispensing preferentially priced drugs obtained pursuant to Section 256b of Title 42 of the United States Code. Contracts between those covered entities and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

(b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy's other drug stock by either physical or electronic means. All records of

acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records.

(c) Drugs obtained by a pharmacy to be dispensed to patients of a covered entity pursuant to Section 256b of Title 42 of the United States Code that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy shall be returned to the distributor from which they were obtained. For the purposes of this section, a change in circumstances includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity.

(d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license.

(e) Neither a covered entity nor a pharmacy shall be required to obtain a license as a wholesaler based on acts reasonably necessary to fully participate in the drug purchase program established by Section 256b of Title 42 of the United States Code.

4126.5. Furnishing Dangerous Drugs by Pharmacy

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

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

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

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

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

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

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

(7) To another pharmacy under common control.

(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.

4126.9. Recall of Nonsterile Compounded Drug Products – Requirements

(a) A pharmacy that issues a recall notice regarding a nonsterile compounded drug product shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply:

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

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

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

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

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

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

(c) A pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy shall report the event to MedWatch within 72 hours of the pharmacy being advised.

Article 7.5 Compounded Sterile Drug Products

4127. License to Compound Sterile Drug Products Required

(a) A pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article.

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

4127.1. License to Compound Injectable Sterile Drug Products Required

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

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

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

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.

(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

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

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:

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

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

(h) This section shall become operative on July 1, 2014.

4127.2. Nonresident Pharmacy – License to Compound and Ship Injectable Sterile Drug Products into California Required

(a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

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

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.

(4) Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

(4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

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

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

(2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.

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

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

(h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

(i) This section shall become operative on July 1, 2014.

4127.3. Cease and Desist Order; Hearing

(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

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

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4127.4. Fine for Violation

Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars (\$2,500) per occurrence pursuant to a citation issued by the board.

4127.6. Article Operative Upon Allocation of Positions

This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.

4127.7. Compounding Sterile Injectables from Nonsterile Ingredients; Requirements

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

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

- (b) An ISO class 5 cleanroom.
- (c) A barrier isolator that provides an ISO class 5 environment for compounding.

4127.8. Temporary License to Compound Injectables

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

4127.9. Pharmacies That Compound Sterile Drug Products; Recalls; Requirements

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

- (1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
 - (2) The recalled drug was dispensed, or is intended for use, in this state.
- (b) A recall notice issued pursuant to subdivision (a) shall be made as follows:
- (1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.
 - (2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.
 - (3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

Article 7.6. Centralized Hospital Packaging Pharmacies

4128. Centralized Hospital Packaging

(a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions,

for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.

(2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

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

4128.2. Specialty License Required; Application; Fees

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

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

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

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

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

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

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

(h) Until July 1, 2017, the fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars (\$600) and may be increased by the board to eight hundred dollars (\$800).

(Amended by Stats. 2016, Ch. 799, Sec. 24. Effective January 1, 2017.)

4128.3. Preparing and Storing Limited Quantity of Unit Dose Drugs in Advance of a Patient-Specific Prescription

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

4128.4. Barcode Required; Information Retrievable Upon Reading Barcode *(Effective September 2, 2015)*

(a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient's bedside using barcode medication administration software.

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.

4128.5. Labeling for Unit Dose Medications

(a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall display a human-readable label that contains all of the following:

- (1) The date that the medication was prepared.
- (2) The beyond-use date.
- (3) The established name of the drug.
- (4) The quantity of each active ingredient.
- (5) Special storage or handling requirements.
- (6) The lot number or control number assigned by the centralized hospital packaging pharmacy.
- (7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

- (1) The components used in the drug product.
- (2) The expiration date of each of the drug's components.
- (3) The National Drug Code Directory number.

(Amended by Stats. 2015, Ch. 241, Sec. 3. Effective September 2, 2015.)

4128.6. Compounding

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

4128.7. Integrity, Potency, Quality and Labeled Strength of Unit Dose Drug Products

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

Article 7.7. Outsourcing Facilities

4129. Outsourcing Facility – License Required

(a) A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.

(e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients.

4129.1. Licensing Requirements

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

4129.2. Nonresident Outsourcing Facility – License Required

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) (A) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(B) For purposes of this paragraph, "state" refers to the state in which the nonresident outsourcing facility resides.

(3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

(e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.

(3) A copy of any complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.

4129.3. Board Report to Legislature

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

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

(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.

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

(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

4129.4. Cease and Desist Order

(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

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

(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4129.5. Violation Fine

Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars (\$5,000) per occurrence pursuant to a citation issued by the board.

4129.8. Temporary License

The board, at its discretion, may issue a temporary license to an outsourcing facility upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for

purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

4129.9. Recall – Notice Required

(a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:

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

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

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

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

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

Article 9. Hypodermic Needles and Syringes

4141. Furnishing without License

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

4142. Prescription Required

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

4143. Exemption: Sale to Other Entity, Physician, etc.

This article shall not apply to the sale of hypodermic syringes and needles at wholesale by pharmacies, drug wholesalers, drug manufacturers or manufacturers and dealers in surgical instruments to pharmacies, physicians, dentists, podiatrists, veterinarians, or persons to whom a license has been issued under this article.

4144.5. Industrial Use; Exception

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

4145.5. Conditions for Furnishing Hypodermic and Syringes for Human Use and Specified Animal Use without a Prescription

(a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the 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 and until January 1, 2021, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on 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 counsel consumers on safe disposal and provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards for collection and disposal of medical sharps waste.

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

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

(f) Until January 1, 2021, a pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time

of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

- (1) Access drug treatment.
- (2) Access testing and treatment for HIV and hepatitis C.
- (3) Safely dispose of sharps waste.

4146. Needle/Syringe Return in Sharps Container

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

4147. Disposal of Needle or Syringe

(a) For the purposes of this section, "playground" means any park or outdoor recreational area specifically designed to be used by children that has play equipment installed or any similar facility located on public or private school grounds or county parks.

(b) Any hypodermic needle or syringe that is to be disposed of, shall be contained, treated, and disposed of, pursuant to Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code.

(c) It is unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school.

(d) A person who knowingly violates subdivision (c) is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than two hundred dollars (\$200) and not more than two thousand dollars (\$2,000), or by imprisonment in a county jail for up to six months, or by both that fine and imprisonment.

(e) Subdivision (c) does not apply to the containment, treatment, and disposal of medical sharps waste from medical care or first aid services rendered on school grounds, nor to the containment, treatment, and disposal of hypodermic needles or syringes used for instructional or educational purposes on school grounds.

4148.5. Confiscation if Found Outside Licensed Premises

All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144.5, or 4145.5, or under Section 11364, 121349, or 121349.1 of the Health and Safety Code.

4149. License Required for Nonresident Distributor of Needles or Syringes

(a) A nonresident distributor shall not sell or distribute hypodermic needles or syringes in this state without obtaining a license from the board pursuant to Section 4141.

(b) Notwithstanding subdivision (a), a license is not required if the nonresident distributor sells or distributes solely through a person who is

licensed as a wholesaler or third-party logistics provider pursuant to Section 4160.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident distributor pursuant to this article to serve as evidence that the entity is doing business within this state.

Article 10. Pharmacy Corporations

4150. Definitions

(a) A pharmacy corporation means a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, so long as that corporation and its shareholders, officers, directors, and employees rendering professional services who are pharmacists are in compliance with the Moscone-Knox Professional Corporation Act, this article, and all other statutes and regulations now or hereafter enacted or adopted pertaining to the corporation and the conduct of its affairs.

(b) With respect to a pharmacy corporation, the governmental agency referred to in the Moscone-Knox Professional Corporation Act is the Board of Pharmacy of the State of California.

4151. Licensure Requirements

Each shareholder, director, and officer of a pharmacy corporation, except an assistant secretary and an assistant treasurer, shall be a licensed person as defined in Section 13401 of the Corporations Code.

4152. Corporate Name Requirements

The name of a pharmacy corporation and any name or names under which it may render professional services shall contain the word "pharmacist," "pharmacy," or "pharmaceutical" and wording or abbreviations denoting corporate existence.

4153. Shareholder Income While Disqualified

The income of a pharmacy corporation attributable to professional services rendered while a shareholder is a disqualified person, as defined in Section 13401 of the Corporations Code, shall not in any manner accrue to the benefit of the shareholder or his or her shares in the pharmacy corporation.

4154. Regulations Authorized

The board may adopt and enforce regulations to carry out the purposes and objectives of this article, including regulations requiring (a) that the bylaws of a pharmacy corporation shall include a provision whereby the capital stock of the corporation owned by a disqualified person, as defined in Section 13401 of the Corporations Code, or a deceased person, shall be sold to the corporation or to the remaining shareholders of the corporation within the time as the regulations may provide, and (b) that a pharmacy corporation shall provide adequate

security by insurance or otherwise for claims against it by its patients or clients arising out of the rendering of professional services.

4155. Corporate Form Not Required

Nothing in this article shall be construed as requiring the applicant or holder of a pharmacy permit pursuant to Section 4110 to be a pharmacy corporation.

4156. Unprofessional Conduct by Corporation

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

Article 11. Wholesalers, Third-Party Logistics Providers and Manufacturers

4160. Wholesaler or Third-Party Logistics Provider: License Required

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

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

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

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

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

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

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

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics

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

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

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

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

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

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

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

of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

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

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

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

4161. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Requirements

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

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each

place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

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

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

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

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

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

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

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

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

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars (\$550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

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

4161.5. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider

At such time as federal regulations are promulgated to implement Section 584 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360eee-3), the board shall immediately identify any standard, requirement, or regulation in California law governing interstate commerce that is in conflict with the federal regulations and act to remove the conflict in the manner permitted by law.

4162. Wholesaler or Third-Party Logistics Provider; Surety Bond Requirements

(a) (1) An applicant for the issuance or renewal of a wholesaler license, which is not government owned and operated, shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a third-party logistics provider license, which is not government owned and operated, shall submit a surety bond of ninety thousand dollars (\$90,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(3) For purposes of paragraphs (1) and (2), the board may accept a surety bond less than the amount required under paragraph (1) or (2) if the annual gross receipts of the previous tax year for the wholesaler or third-party logistics provider is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(4) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler or third-party logistics provider, shall not be required to post a surety bond as provided in paragraph (1) or (2).

(5) For licensees subject to paragraph (3) or (4), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

4162.5. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Surety Bond Requirements

(a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000),

or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a nonresident third-party logistics provider license shall submit a surety bond of ninety thousand dollars (\$90,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(3) For purposes of paragraphs (1) and (2), the board may accept a surety bond less than the amount required under paragraph (1) or (2) if the annual gross receipts of the previous tax year for the nonresident wholesaler or the nonresident third-party logistics provider is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

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

(5) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler or a nonresident third-party logistics provider, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

4163. Unauthorized Furnishing by Manufacturer or Wholesaler

(a) A manufacturer, wholesaler, repackager, or pharmacy 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. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

4164. Reports Required

(a) A wholesaler or third-party logistics provider licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all distributions of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, “preferential or contract prices” means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

4165. Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand

A wholesaler or third-party logistics provider licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

4166. Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor Liable for Security and Integrity Until Delivery

(a) A wholesaler that uses the services of a third-party logistics provider or carrier, including, but not limited to, the United States Postal Service or a common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that provider or carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) A third-party logistics provider that uses the services of a carrier, including, but not limited to, the United States Postal Service or a common carrier, shall have in place and comply with written policies and procedures that provide for both of the following:

(1) Verification that the third-party logistics provider, or the owner of the dangerous drugs or dangerous devices stored at the third-party logistics provider, has imposed obligations on the carrier that provide for the security

and integrity of any dangerous drugs or dangerous devices transported by the carrier until the drugs or devices are delivered to the transferee at its premises.

(2) Confirmation, prior to shipping a dangerous drug or dangerous device, that the intended recipient is legally authorized to receive the dangerous drug or dangerous device.

(c) Nothing in this section is intended to affect the liability of a wholesaler, third-party logistics provider, or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

4167. Wholesaler or Third-Party Logistics Provider: Bar on Obtaining Dangerous Drugs or Devices it Cannot Securely Maintain on Licensed Premises

A wholesaler or third-party logistics provider shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, at the place of business licensed by the board.

4168. Board License Required for Local Business License

A county or municipality shall not issue a business license for any establishment that requires a wholesaler or third-party logistics provider license unless the establishment possesses a current wholesaler or third-party logistics provider license issued by the board. For purposes of this section, an “establishment” is the licensee’s physical location in California.

4169. Prohibited Acts

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

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

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received

by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

Article 11.5. Surplus Medication Collection and Distribution Intermediaries

4169.5. Surplus medication Collection and Distribution Intermediary; License

(a) A surplus medication collection and distribution intermediary established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a program established pursuant to Division 116 (commencing with Section 150200) of the Health and Safety Code shall be licensed by the board. The board shall enforce the requirements set forth in Section 150208 of the Health and Safety Code. The license shall be renewed annually.

(b) An application for licensure as a surplus medication collection and distribution intermediary shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is an entity other than a natural person, the application shall state the information as to each person beneficially interested in that entity.

(c) As used in this section, and subject to subdivision (e), the term “person beneficially interested” means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(d) If the applicant is a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, the applicant shall furnish the board with the organization’s articles of incorporation. The applicant shall also furnish the board with the names of the controlling members.

(e) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and if the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (b) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant’s entity. Upon request by the executive officer of the board, the applicant shall furnish the board with the information required by subdivision (b) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(f) The application shall contain a statement to the effect that the applicant or persons beneficially interested have not been convicted of a felony and have not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(g) Upon the approval of the application by the board and payment of a fee in the amount of three hundred dollars (\$300), the executive officer of the board shall issue or renew a license to operate as a surplus medication collection and distribution intermediary, if all of the provisions of this chapter have been complied with. Fees received by the board pursuant to this section shall be deposited into the Pharmacy Board Contingent Fund. An applicant for licensure as a surplus medication collection and distribution intermediary that is government owned or is a nonprofit organization pursuant to subdivision (d) is exempt from the fee requirement.

(h) A surplus medication collection and distribution intermediary licensed pursuant to this section is exempt from licensure as a wholesaler.

(i) A surplus medication collection and distribution intermediary licensed pursuant to this section shall keep and maintain for three years complete records for which the intermediary facilitated the donation of medications to or transfer of medications between participating entities.

Article 12. Prescriber Dispensing

4170. Dispensing by Prescriber: Requirements and Restrictions; Enforcement

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

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

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

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

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

4170.5. Veterinarian in Teaching Hospital May Dispense and Administer Dangerous Drugs and Devices; Requirements

(a) Veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school may dispense and administer dangerous drugs and devices and controlled substances from a common stock.

(b) The veterinary teaching hospital shall designate a pharmacist to be responsible for ordering the drugs for the common stock and the designated pharmacist-in-charge shall be professionally responsible to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, and dispensing occur in a manner that is consistent with the promotion and protection of the health and safety of the public.

(c) The veterinary teaching hospital's pharmacist-in-charge shall develop policies, procedures, and guidelines that recognize the unique relationship between the institution's pharmacists and veterinarians in the control, management, dispensation, and administration of drugs.

(d) The board may inspect a veterinary teaching hospital dispensing or administering drugs pursuant to this section.

4171. Exceptions to Section 4170: Samples; Clinics; Veterinarians; Narcotic Treatment Programs; Certain Cancer Medications

(a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

4172. Storage Requirements

A prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be dispensed in an area that is secure. The Medical Board of California shall, by regulation, define the term "secure" for purposes of this section.

4173. Dispensing by Registered Nurses

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

4174. Dispensing by Pharmacist Upon Order of Nurse Practitioner

Notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner 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.

4175. Processing of Complaints

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

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, naturopathic doctors, or physician assistants pursuant to Section

4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Bureau of Naturopathic Medicine, the Board of Registered Nursing, the Veterinary Medical Board, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

Article 13. Nonprofit or Free Clinics

4180. Purchase of Drugs at Wholesale Only with License: Eligible Clinics

(a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 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.

(c) The board shall synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

4181. License Requirements; Policies and Procedures; Who May Dispense

(a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development,

recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

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

4182. Duties of Professional Director; Consulting Pharmacist Required

(a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

4183. No Professional Dispensing Fee

No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. Dispensing Schedule II Substance by Clinic Prohibited

No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.

4185. Inspection Permitted

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

4186. Automated Drug Delivery Systems

(a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

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

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

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

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

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

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

(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

Article 14. Clinics

4190. Clinic Defined; License Required; Purchase of Drugs at Wholesale: Drug Distribution Service of a Clinic; Information Reported to the Board

(a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and

Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

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

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

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

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

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

4191. Compliance With Department of Public Health Requirements; Who May Dispense Drugs

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

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

4192. Duties of Professional Director; Providing Information to Board

(a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

4193. Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale

No clinic holding a license pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code). No clinic holding a license pursuant to this article shall offer drugs for sale or shall charge or bill for professional services for the dispensing or administering of drugs.

4194. Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

No Schedule II controlled substance shall be dispensed in the clinic. This limitation does not prohibit a physician from dispensing a Schedule II drug to the extent permitted by subdivision (b) of Section 11158 of the Health and Safety Code and all other provisions of law, nor does it prevent the lawful administration of Schedule II drugs on the premises of the clinic.

4195. Inspection Authorized

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

Article 15. Veterinary Food-Animal Drug Retailers

4196. License Required: Temporary Licenses; Persons Authorized in Storage Area; Other Requirements; Board Approval of Designated Representative-in-Charge

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

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

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

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

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

replacements until a designated representative-in-charge is approved by the board.

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

4197. Minimum Standards: Security; Sanitation; Board Regulations; Waivers

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

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

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

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

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

4198. Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

(a) Each veterinary food-animal drug retailer shall have written policies and procedures related to the handling and dispensing of veterinary food-animal drugs by veterinary food-animal drug retailers. These written policies and procedures shall include, but not be limited to, the following:

(1) Training of staff.

(2) Cleaning, storage, and maintenance of veterinary food-animal drugs and equipment.

(3) Recordkeeping requirements.

(4) Storage and security requirements.

(5) Quality assurance.

(b) Each retailer shall prepare and maintain records of training and demonstrated competence for each individual employed or retained by the retailer. These records shall be maintained for three years from and after the last date of employment.

(c) Each retailer shall have an ongoing, documented quality assurance program which includes, but is not limited to:

(1) Monitoring personnel performance.

(2) Storage, maintenance, and dispensing of veterinary food-animal drugs.

(d) The records and documents specified in subdivisions (a) and (b) shall be maintained for three years from the date of making. The records and documents in subdivisions (a), (b), and (c) shall be, at all times during business hours, open to inspection by authorized officers of the law.

(e) To assure compliance with the requirements of this chapter regarding operations of the veterinary food-animal drug retailer, a consulting pharmacist shall visit the veterinary food-animal drug retailer regularly and at least quarterly. The consulting pharmacist shall be retained either on a volunteer or paid basis to review, approve, and revise the policies and procedures of the veterinary food-animal drug retailer, and assure compliance with California and federal law regarding the labeling, storage, and dispensing of veterinary food-animal drugs.

The consulting pharmacist shall certify in writing at least twice a year whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter. The most recent of the written certifications shall be submitted with the annual renewal application of a veterinary food-animal drug retailer license.

4199. Labeling Requirements; Maintaining Prescription Records

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

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

Article 16. Applications

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

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

- (1) Is at least 18 years of age.
- (2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or
(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.
- (3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.
- (4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

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

(6) Has passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

4200.1 Multiple Failures of License Examination; Additional Education Requirements

(a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

4200.2. California Practice Standards and Jurisprudence Examination for Pharmacists; Required Inclusions

When developing the California Practice Standards and Jurisprudence Examination for Pharmacists, the board shall include all of the following:

(a) Examination items to demonstrate the candidate's proficiency in patient communication skills.

(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.

4200.3. Examination Process to be Reviewed Regularly; Required Standards

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

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

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

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

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

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

4200.4. Retaking National Examination After Failure; Waiting Period

An applicant who fails 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.

4200.5. Retired Licensee: Eligibility; Bar on Practice; Requirement for Restoration to Active Status

(a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. The board shall not issue a retired license to a pharmacist whose license has been revoked.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A

pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."

(c) The holder of a retired license shall not be required to renew that license.

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

4201. Application Form: Required Information; Authority Granted by License; Reporting Changes in Beneficial Ownership

(a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein or any person with management or control over the license.

(b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

(Amended by Stats. 2015, Ch. 303, Sec. 7. Effective January 1, 2016.)

4202. Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline

(a) The board may issue a pharmacy technician license to an individual if 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 a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

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

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

(e) Once an individual is licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

4203. Non-Profit Clinic License Application: Form; Investigation

(a) Each application for a license under Section 4180 shall be made on a form furnished by the board. The form of application for a license under Section 4180 shall contain the name and address of the applicant, whether the applicant is licensed as a primary care clinic as defined in this code, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.

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

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under this article, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4180. The license shall be renewed annually on or before December 31 of each year upon payment of the renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable.

4203.5. Clinic Application

(a) Notwithstanding any other law, when a clinic applicant submits either type of application described in subdivision (b), the board shall issue a license or incorporate the reported changes, as appropriate, within 30 days of receipt of a completed application and payment of any prescribed fees.

(b) This section applies to the following types of applications:

(1) A new clinic license application filed under Section 4180.

(2) Applications to report changes to an existing site licensed under Section 4180, including, but not limited to, changes in professional director, clinic administrator, corporate officers, change of location, or change of address.

(c) This section shall not be construed to limit the board's authority to conduct an investigation to determine whether applicants and the premises for which an application is made qualify for a license.

4204. Surgical Clinic Application: Form; Investigation

(a) Each application for a license under Section 4190 shall be made on a form furnished by the board. The form of application for a license under this article shall contain the name and address of the applicant, whether the applicant is licensed, the type of services the facility will offer, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.

(b) Each initial application shall contain a statement from a consulting pharmacist certifying that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of health and safety of the public. Upon the filing of the application and the payment of a fee in subdivision (s) of Section 4400, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for a license. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license. The board shall not however, investigate any matters connected with the operation of a premises, including operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made do not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under Section 4190, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4190. The license shall be renewed annually upon payment of a renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable.

4205. Sale or Dispensing of Hypodermic Syringes and Needles: When Separate License Required; Form and Content of Application; Renewability; Discipline

(a) A license issued pursuant to Section 4110, 4120, 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use.

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of Article 9 (commencing with Section 4140) of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

4207. Investigation by Board

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

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

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

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

4208. Intern Pharmacist License

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

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

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

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

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

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

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

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

(e) A person who has not completed the experience requirements necessary to be eligible for the licensure examination may have his or her intern license extended for a period of up to two years at the discretion of the board if he or

she is able to demonstrate his or her inability to exercise the privileges of the intern license during the initial license period.

4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam

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

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

(3) This pharmacy practice experience shall include 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and shall include pharmacy practice experience in both a community and institutional pharmacy practice setting.

(b) An intern pharmacist shall submit proof of his or her pharmacy practice experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision the experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Pharmacy practice experience earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of pharmacy practice experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and has pharmacy practice experience in both a community and institutional pharmacy practice setting. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(d) An applicant for the examination who has graduated after January 1, 2016, from an ACPE accredited college of pharmacy or school of pharmacy recognized by the board shall be deemed to have satisfied the pharmacy practice experience requirements specified in subdivisions (a) and (b).
(Amended by Stats. 2015, Ch. 147, Sec. 1. Effective January 1, 2016.)

4210. Advanced Practice Pharmacist License

(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).

Article 17. Continuing Education

4231. Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

(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.

4232. Content of Courses

(a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

4233. Advanced Practice Pharmacist; Continuing Education Requirement

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.

4234. Exceptions: Emergencies; Hardship

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

Article 18. Poisons

4240. California Hazardous Substances Act; Application of Act

(a) The California Hazardous Substances Act, Chapter 4 (commencing with Section 108100) of Part 3 of Division 104 of the Health and Safety Code, applies to pharmacies and pharmacists and any other person or place subject to the jurisdiction of the board.

(b) The board may enforce that act when necessary for the protection of the health and safety of the public if prior regulatory notice is given in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). Board enforcement shall focus on those hazardous substances that relate significantly to or overlap the practice of pharmacy.

(c) "Poison" as used in this chapter refers to a category of hazardous substances defined in Section 108125 of the Health and Safety Code. The board may by regulation make the category more specific.

Article 19. Disciplinary Proceedings

4300. Revocation and Suspension: Authority; Conditions; Issuance of Probationary License; Application of Administrative Procedure Act; Judicial Review

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

4300.1. Board Authority to Render a Decision on a License

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

4301. Obtaining License by Fraud or Misrepresentation; Unprofessional Conduct

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

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

of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

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

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

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

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

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

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

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with

the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

4301.1. Investigation Priority – Greatest Threat of Patient Harm

In order to ensure that the board's resources are maximized for the protection of the public health and safety, the board shall prioritize its investigative and prosecutorial resources to ensure that pharmacists representing the greatest threat of patient harm are identified and disciplined expeditiously.

4301.5. Pharmacist License; Out-of-State Suspension or Revocation to Apply to California License

(a) If a pharmacist possesses a license or is otherwise authorized to practice pharmacy in any other state or by an agency of the federal government, and that license or authority is suspended or revoked, the pharmacist's license shall be suspended automatically for the duration of the suspension or revocation, unless terminated or rescinded as provided in subdivision (c). The board shall notify the pharmacist of the license suspension and of his or her right to have the issue of penalty heard as provided in this section.

(b) Upon its own motion or for good cause shown, the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the pharmacy profession.

(c) The issue of penalty shall be heard by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law judge, or by the board sitting with an administrative law judge, at the board's discretion. A pharmacist may request a hearing on the penalty and that hearing shall be held within 90 days from the date of the request. If the order suspending or revoking the pharmacist's license or authority to practice pharmacy is overturned on appeal, any discipline ordered pursuant to this section shall automatically cease. Upon the showing to the administrative law judge, board, or committee of the board by the pharmacist that the out-of-state action is not a basis for discipline in California, the suspension shall be rescinded.

If an accusation for permanent discipline is not filed within 90 days of the suspension imposed pursuant to this section, the suspension shall automatically terminate.

(d) The record of the proceedings that resulted in the suspension or revocation of the pharmacist's license or authority to practice pharmacy, including a transcript of the testimony therein, may be received in evidence.

(e) If a summary suspension has been issued pursuant to this section, the pharmacist may request that the hearing on the penalty conducted pursuant to subdivision (c) be held at the same time as a hearing on the accusation.

4302. Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest, or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

4303. Nonresident Pharmacy: Grounds for Discipline

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

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

4303.1. Outsourcing Facility – License Canceled, Revoked or Suspended by Operation of Law

If the federal Food and Drug Administration (FDA) cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant to Section 4129.2 shall be immediately canceled, revoked, or suspended by operation of law.

4304. Nonresident Wholesaler; Authority to Discipline

The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code.

4305. Disciplinary Grounds: Failure of Pharmacy or Pharmacist to Notify Board of Termination of Pharmacist-in-Charge; Continuing to Operate Without Pharmacist

(a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act as the pharmacist-in-charge of a pharmacy, or by any pharmacy to

notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in Sections 4101 and 4113 shall constitute grounds for disciplinary action.

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

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

4305.5. Disciplinary Grounds: Failure of Wholesaler, Veterinary Food-Animal Drug Retailer or Third-Party Logistics Provider to Notify Board of Termination of Designated Representative-in-Charge or Responsible Manager; Continuing to Operate Without Designated Representative-in-Charge or Responsible Manager

(a) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge or responsible manager. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, that willfully fails to notify the board of the termination of employment of the designated representative-in-charge or responsible manager at its licensed place of business, and that continues to operate the place of business in the absence of the designated representative-in-charge or responsible manager for that place of business shall be subject to summary suspension or revocation of its license as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer at that place of business.

(c) A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, or a responsible manager of a third-party logistics provider, who terminates his or her employment at the licensed place of business, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

4306. Violation of Professional Corporation Act as Unprofessional Conduct

It shall constitute unprofessional conduct and a violation of this chapter for any person licensed under this chapter to violate, attempt to violate, directly or indirectly, or assist in or abet the violation of, or conspire to violate, any

provision or term of this article, the Moscone-Knox Professional Corporation Act, or any regulations duly adopted under those laws.

4306.5. Acts or Omissions by Pharmacist: Unprofessional Conduct

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

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

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

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

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

4306.6. Mitigating Factors for Pharmacist-in-Charge Reporting Violations of Others

If the board disciplines a pharmacist-in-charge for the violation of a state or federal law or regulation committed by another person and the pharmacist-in-charge reported to the board that violation or suspected violation, the board shall use the report as a mitigating factor if all of the following conditions are met:

(a) The pharmacist-in-charge did not engage, either directly or indirectly, in any conduct that violated any state or federal law or regulation pertaining to the practice of pharmacy.

(b) The pharmacist-in-charge did not permit, encourage, approve of, either tacitly or implicitly or through willful ignorance, any conduct committed by another person that violated state or federal law or regulation pertaining to the practice of pharmacy.

(c) The pharmacist-in-charge reported the violation, or suspected violation, of any state or federal law or regulation pertaining to the practice of pharmacy to the board as soon as reasonably possible following the discovery of the violation.

(d) The pharmacist-in-charge took all actions reasonably necessary to stop and remedy the violation, or suspected violation, of any state or federal law or regulation pertaining to the practice of pharmacy as soon as reasonably possible following the discovery of the violation.

4307. Individuals with Denied, Revoked, Suspended, etc. Licenses Prohibited From Pharmacy Ownership or Association with Board Licensed Entities

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

4308. Prohibited Association: Notification of Affected Licensees Known to Board

Whenever a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position of management or control of a licensee as provided by Section 4307, the board shall, in each case where it has that information, notify in writing each licensee for whom the person is a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of the prohibition. The board shall send the notification to the licensee's address of record. The licensee shall have 30 days from the date that the notice is sent to remove and replace the prohibited person and, where appropriate, file a change of permit to reflect that change.

4309. Petition for Reinstatement, etc. of Disciplined License: Time for Filing; Contents; Investigation; Hearing; Factors to be Considered; Effect of Ongoing Criminal Sentence, Accusation, or Petition to Revoke Probation

(a) A person whose license has been revoked or suspended or who has been placed on probation may petition the board for reinstatement or modification of penalty, including modification or termination of probation, after not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

- (1) At least three years for reinstatement of a revoked license.
- (2) At least two years for early termination of probation of three years or more.
- (3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

(b) The petition shall state any facts required by the board, and the petition shall be accompanied by two or more verified recommendations from holders of licenses issued by the board to which the petition is addressed, and two or more recommendations from citizens, each having personal knowledge of the disciplinary penalty imposed by the board and the activities of the petitioner since the disciplinary penalty was imposed.

(c) The petition may be heard by the board sitting with an administrative law judge, or a committee of the board sitting with an administrative law judge, or the board may assign the petition to an administrative law judge. Where the petition is heard by a committee of the board sitting with an administrative law judge or by an administrative law judge sitting alone, the decision shall be subject to review by the board pursuant to Section 11517 of the Government Code.

(d) In considering reinstatement or modification of penalty, the board, committee of the board, or the administrative law judge hearing the petition may consider factors including, but not limited to, all of the following:

- (1) All the activities of the petitioner since the disciplinary action was taken.
- (2) The offense for which the petitioner was disciplined.
- (3) The petitioner's activities during the time the license was in good standing.
- (4) The petitioner's documented rehabilitative efforts.
- (5) The petitioner's general reputation for truth and professional ability.

(e) The hearing may be continued from time to time as the board, committee of the board, or the administrative law judge designated in Section 11371 of the Government Code finds necessary.

(f) The board, committee of the board, or administrative law judge may impose necessary terms and conditions on the licensee in reinstating the license.

(g) No petition under this section shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole. No petition shall be considered while there is an accusation or petition to revoke probation pending

against the person. The board may deny without a hearing or argument any petition filed pursuant to this section within a period of two years from the effective date of the prior decision following a hearing under this section.

(h) Nothing in this section shall be deemed to amend or otherwise change the effect or application of Sections 822 and 823.

(i) The board may investigate any and all matters pertaining to the petition and documents submitted with or in connection with the application.

4310. Notice of Denial of Application: Petition for Licensure; Application of Administrative Procedure Act

Immediately upon the denial of any application for a license the board shall notify the applicant in writing. Within 10 days after the board mails the notice, the applicant may present his or her written petition for a license to the board. Upon receipt by the board of the written petition, proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

4311. Suspension of License for Felony Conviction: Automatic Suspension; Summary Suspension; Other Suspensions; Applicable Proceedings

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) The hearing to determine whether a felony conviction is substantially related for purposes of an interim suspension under this subdivision shall be separate from any hearing on an accusation under the Administrative Procedure Act, except where the licensee elects to proceed under paragraph (2) of subdivision (d), or where the board has filed and served an accusation as provided by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of hearing as required by that chapter. The hearing on whether the felony conviction is substantially related shall be heard either by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law judge, or by the board sitting with an administrative law judge, at the board's discretion, and shall be

subject to review by the board, at its discretion. However, if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case. Except where a person proceeds under paragraph (2) of subdivision (d), or the board proceeds with an accusation at the same time, any suspension imposed under this subdivision shall continue until an accusation is filed under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and a final decision is rendered by the board.

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

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

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

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

certified copy of the criminal conviction shall be conclusive proof of the fact of the conviction.

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

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

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

4312. Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock

(a) The board may cancel the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or

dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility is located, authorizing the board to enter the wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, “closed” means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

4313. Evidence of Rehabilitation; Priority of Public Protection

In determining whether to grant an application for licensure or whether to discipline or reinstate a license, the board shall give consideration to evidence of rehabilitation. However, public protection shall take priority over

rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence.

4314. Orders of Abatement

(a) The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. Letter of Admonishment

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

(b) The executive officer, or his or her designee, may issue a letter of admonishment to an applicant for licensure who has committed any violation of law that the board deems, in its discretion, does not merit the denial of a license or require probationary status under Section 4300. The letter of admonishment may be issued concurrently with a license.

(c) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(d) The letter of admonishment shall inform the licensee or applicant that within 30 days of service of the order of admonishment the licensee or applicant may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

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

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

(C) The office conference is intended to be an informal proceeding and shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), or Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

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

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

(2) Comply with the letter of admonishment and, if required, submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(e) The letter of admonishment shall be served upon the licensee or applicant personally or by certified mail at his or her address of record with the board. If the licensee or applicant is served by certified mail, service shall be effective upon deposit in the United States mail.

(f) The licensee or applicant shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

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

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

(2) Institute disciplinary proceedings pursuant to this article.

(h) The issuance of a letter of admonishment pursuant to subdivision (b) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

4316. Board Authorized to Issue Cease and Desist Orders

(a) The board is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure.

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

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

Article 20. Prohibitions and Offenses

4320. Penalties for Violation of Pharmacy Law: Actions Authorized; Who May File Actions

(a) The penalties prescribed in this chapter may be recovered in any court having jurisdiction, by a civil action instituted by the board in the name of the State of California, or by criminal prosecution upon complaint being made.

(b) The district attorney of the county wherein violations of this chapter occur shall conduct all felony prosecutions at the request of the board. The district attorney of the county or city attorney of the city wherein violations of this chapter occur shall conduct all other actions and prosecutions at the request of the board.

4321. Penalties: Misdemeanors; Infractions

(a) Any person who knowingly violates any of the provisions of this chapter, when no other penalty is provided, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine of not less than two hundred dollars (\$200), and not more than two thousand dollars (\$2,000), or by imprisonment of not less than 30 days nor exceeding six months, or by both that fine and imprisonment.

(b) In all other instances, any person who violates any of the provisions of this chapter, when no other penalty is provided, is guilty of an infraction, and upon conviction thereof may be punished by a fine not to exceed one thousand dollars (\$1,000).

4322. Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties

Any person who attempts to secure or secures licensure for himself or herself or any other person under this chapter by making or causing to be made any false representations, or who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars (\$5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment.

4323. Misdemeanor; False Representation of Self as a Physician, Agent of Physician, etc. to Obtain Drug

Every person who, in order to obtain any drug, falsely represents himself or herself to be a physician or other person who can lawfully prescribe the drug, or falsely represents that he or she is acting on behalf of a person who can lawfully prescribe the drug, in a telephone or electronic communication with a pharmacist, shall be punished by imprisonment in the county jail for not more than one year.

4324. Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription

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

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

4325. Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank

(a) No person other than a physician, dentist, podiatrist, veterinarian, pharmacist, or other person authorized by law to dispense, administer, or prescribe controlled substances, or the person's agent acting under authorization by the person to print prescription blanks, and acting in the regular practice of the person's profession, shall knowingly and willfully manufacture, copy, reproduce, or possess, or cause to be manufactured, copied, reproduced, or possessed, any prescription blank that purports to bear the name, address, and federal registry or other identifying information of a physician, dentist, podiatrist, veterinarian, or other person authorized by law to dispense, administer, or prescribe controlled substances.

(b) Every person who violates this section shall be guilty of a misdemeanor.

**4326. Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.;
Unlawful Use of Needle or Syringe Obtained from Another**

(a) Any person who obtains a hypodermic needle or hypodermic syringe by a false or fraudulent representation or design or by a forged or fictitious name, or contrary to, or in violation of, any of the provisions of this chapter, is guilty of a misdemeanor.

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

**4327. Misdemeanor: Sale, Dispensing, or Compounding While Under the
Influence of Drugs or Alcoholic Beverages**

Any person who, while on duty, sells, dispenses or compounds any drug while under the influence of any dangerous drug or alcoholic beverages shall be guilty of a misdemeanor.

**4328. Misdemeanor: Permitting Compounding, Dispensing, or Furnishing
by Non-Pharmacist**

Except as otherwise provided in this chapter, any person who permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor.

**4329. Misdemeanor: Non-Pharmacist Acting as Manager, Compounding,
Dispensing or Furnishing Drugs**

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

**4330. Misdemeanor: Non-Pharmacist Owner Failing to Place Pharmacist
in Charge, Dispensing or Compounding Except by Pharmacist,
Interfering with Pharmacist-in-Charge**

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

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

4331. Misdemeanor: Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Designated Representative in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Designated Representative

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

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

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

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

4332. Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Reports

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

4333. Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records is Misdemeanor

(a) All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection

by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

(b) Any person who willfully fails to comply with subdivision (a) is guilty of a misdemeanor, and upon conviction thereof, shall be punished by a fine not exceeding two hundred dollars (\$200). Any person convicted of a second or subsequent offense shall be punished by a fine of not less than two hundred dollars (\$200) and not more than four hundred dollars (\$400).

(c) (1) Notwithstanding subdivisions (a) and (b), the board may, upon written request, grant a waiver of the requirement that the records described in subdivisions (a) and (b) be maintained on the licensed premises or, in the event the pharmacy discontinues business, that the records be maintained in a board licensed facility. A person who maintains records in compliance with that waiver is not subject to the penalties set forth in subdivision (b).

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

4335. Knowingly Failing to Arrange for Disposition of Stock of Closed or Discontinued Business: Misdemeanor

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

4336. Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

(a) Every person who knowingly or willfully violates Section 4055, 4059, 4060, 4061, 4062, 4063, 4064, 4065, 4077, 4080, 4081, 4083, or 4332 with respect to dangerous drugs by use of a minor as an agent is guilty of a felony.

(b) Nothing contained in this section shall apply to a pharmacist furnishing dangerous drugs pursuant to a prescription.

4337. Distribution of Fines Collected

Except as otherwise specified, all fines collected for violations of this chapter shall be paid as follows: one-half into the State Treasury to the credit of the Contingent Fund of the Board of Pharmacy of the State of California and one-half to the treasurer of the jurisdiction in which the misdemeanor is prosecuted, to be deposited in the same fund as fines for other misdemeanors occurring in that jurisdiction are deposited.

4338. Additional Fines May be Assessed

In addition to any fine assessed under Section 4321, the judge may assess a fine not to exceed seventy dollars (\$70) against any person who violates Section 4140 or 4142, with the proceeds of this fine to be used in accordance with Section 1463.23 of the Penal Code. The court shall, however, take into consideration the defendant's ability to pay and no defendant shall be denied probation because of his or her inability to pay the fine permitted under this section.

4339. Board Action to Enjoin Violation of Pharmacy Law; Exception for Certain Drugs and Devices

(a) The board may bring an action to enjoin the violation of any provision of this chapter in any superior court in and for the county in which the violation has occurred. Any action shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the board shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or irreparable damage or loss. The action shall be brought in the name of the people of the State of California.

(b) Nothing in this section shall permit the bringing of any action with respect to any drug or product not subject to Section 4022 that is packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(c) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.

4340. Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

It is unlawful for any nonresident pharmacy that is not registered pursuant to Section 4112 or for any person who is a resident of this state to advertise the pharmacy services of any pharmacy, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

4341. Advertisement of Prescription Drugs or Devices

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

4342. Actions by Board to Prevent Sales of Preparations or Drugs Lacking Quality of Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States

Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336.

4343. Buildings: Prohibition Against the Use of Certain Signs Unless Licensed Pharmacy Within

No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110.

Article 21. Pharmacists Recovery Program

4360. Impaired Pharmacists: Legislative Intent

The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

4361. Definitions

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

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

4362. Function of Program: Board Referrals; Voluntary, Confidential Participation

(a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the

pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

4364. Criteria for Participation to be Established by Board

(a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4365. Contracting with Employee Assistance Program: Selection

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

4366. Function of the Employee Assistance Program

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

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

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

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

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

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

4369. Board Referrals to Program: Written Information Provided to Licensee; Termination for Non-Compliance; Report to Board of Termination; Authority to Discipline

(a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

4371. Review of Program Activities

(a) The executive officer of the board shall designate a program manager of the pharmacists recovery program. The program manager shall have background experience in dealing with substance abuse issues.

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

(c) The program manager shall work with the contractor administering the pharmacists recovery program to evaluate participants in the program according to established guidelines and to develop treatment contracts and evaluate participant progress in the program.

4372. Confidential Records; Exception for Disciplinary Proceeding

All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

4373. Immunity from Civil Liability

No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

Article 22. Unfair Trade Practices

4380. Resale of Preferentially Priced Drugs: Prohibition; Exceptions

(a) The resale, by any person, of drugs acquired at preferentially low prices permitted under federal law only because of the Nonprofit Institutions Act (15 U.S.C. Sec. 13c) is prohibited except in any of the following instances:

(1) When for the person's own use, as defined by the federal courts in *Abbott Labs. v. Portland Retail Druggists* (425 U.S. 1, 47 L. Ed. 2d 537) and *DeModena v. Kaiser Foundation Health Plan, Inc.* (743 F. 2d 1388).

(2) When sold to a purchaser also eligible for those prices under the Nonprofit Institutions Act, that controls, is controlled by, or is under common control with, the seller, and that purchases the products for its own use, as defined in paragraph (1).

(3) When sold to a walk-in customer pursuant to a prescription, provided that those sales represent less than 1 percent of the drugs purchased by the seller for its own use in this state.

(b) Nothing in this article prohibits the resale of drugs to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need.

4381. Violation of Article as Unfair Competition; Private Actions Authorized; Triple Damages and Attorneys' Fees; Proof Required

(a) A violation of this article is an act of unfair competition within the meaning of Chapter 5 (commencing with Section 17200) of Part 2 of Division 7, and this article is enforceable as provided in that chapter.

(b) In addition thereto, any person or trade association may bring an action to enjoin and restrain any violation of this article and to recover actual damages, if any.

(c) In an action for injunctive relief under this article, it is not necessary to allege or prove actual damages or the threat thereof, or actual injury or the threat thereof, to the plaintiff. In addition to injunctive relief, the plaintiff in any action shall recover three times the amount of his or her actual damages, if any, as well as three times the actual damages, if any, sustained by any person who has assigned to the plaintiff a claim for damages resulting from a violation of this section. In any action under this article in which judgment is entered against the defendant, the plaintiff shall be awarded reasonable attorneys' fees together with the costs of suit.

(d) In issuing an injunction against a violation under this article, the court may, in its discretion, include any other restraint it deems expedient in order to deter the defendant from and ensure against future violations of this article.

(e) Proof of malice or intent to harm competition is immaterial to sustain a cause of action under this article.

4382. Board May Audit Sales to Walk-In Customers

The board may audit persons for compliance with the limits established in paragraph (3) of subdivision (a) of Section 4380 except that in the case of a facility or pharmacy that predominately serves members of a prepaid group practice health care service plan, those audits may be undertaken solely by the Department of Managed Health Care pursuant to its authority to audit those plans.

Article 23. Revenue and Renewal

4400. Fees¹

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 or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(g) The fee for a hypodermic license 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 a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(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 ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).

(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 sterile compounding pharmacy license 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) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

(¹Amended by Stats. 2016, Ch. 799, Sec. 25. Effective January 1, 2017. Inoperative July 1, 2017. Repealed as of January 1, 2018, by its own provisions. See later operative version added by Sec. 26 of Stats. 2016, Ch. 799.)

4400. Fees²

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

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

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

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

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

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

a pharmacist biennial renewal shall be three hundred sixty dollars (\$360) and may be increased to five hundred five dollars (\$505).

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

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

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

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

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

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

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

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

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

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

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars (\$165) and may be increased to two hundred thirty dollars (\$230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).
(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

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

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

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

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

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

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

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

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

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to three thousand three hundred thirty-five dollars (\$3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to three thousand one hundred eighty dollars (\$3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a

reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

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

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

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

(z) This section shall become operative on July 1, 2017.

(²Repealed (in Sec. 25) and added by Stats. 2016, Ch. 799, Sec. 26. Effective January 1, 2017. Section operative July 1, 2017, by its own provisions.)

4401. Pharmacist: Biennial Renewal

Every pharmacist who desires to retain his or her license on the books of the board shall biennially pay to the executive officer of the board the renewal fee, established by the board, within the limits prescribed by this chapter. In return for the payment of the renewal fee, a certificate of renewal shall be issued.

4402. Cancellation: Of Pharmacist after Non-Renewal for Three Years; All Other Licenses after 60 Days

(a) Any pharmacist license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

(b) (1) Any pharmacist whose license is canceled pursuant to subdivision (a) may obtain a new license if he or she takes and passes the examination that is required for initial license with the board.

(2) The board may impose conditions on any license issued pursuant to this section, as it deems necessary.

(c) A license that has been revoked by the board under former Section 4411 shall be deemed canceled three years after the board's revocation action, unless the board has acted to reinstate the license in the interim.

(d) This section shall not affect the authority of the board to proceed with any accusation that has been filed prior to the expiration of the three-year period.

(e) Any other license issued by the board may be canceled by the board if the license is not renewed within 60 days after its expiration. Any license canceled under this subdivision may not be reissued. Instead, a new application will be required.

4403. Reissuance without Payment of Fees Prohibited

The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.

4404. Reissuance of Lost or Destroyed License; Proof of Loss, etc.

If any license issued under this chapter is lost or destroyed, or if any person desires a reissuance of his or her license, the board may reissue it, subject to Section 4403, upon application therefor, and the submission of satisfactory proof, if required by the board, that the license has been lost or destroyed, or if the license has not been lost or destroyed, upon the surrender of the old license.

4405. Disposition of Fines

All fines recoverable under this chapter shall be paid by the magistrate receiving the same to the board, except where other provision is made in this chapter for the disposition thereof.

4406. Report of Fees Collected

All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the Controller and at the same time the entire amount shall be paid into the State Treasury and shall be credited to the Pharmacy Board Contingent Fund which is hereby created. This contingent fund shall be available, upon appropriation of the Legislature, for the use of the board.

4407. Compensation of Members

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

4409. Contribution to California Pharmacist Scholarship and Repayment Program at License Renewal

At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4110 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a contribution of at least twenty-five dollars (\$25), to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 2 (commencing with Section 128198) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be paid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128198.5 of the Health and Safety Code.

Article 24. Prescription Rates for Medicare Beneficiaries

4425. Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring

(a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Care Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Health Care Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Health Care Services shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Health Care Services shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding

the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

4426. Department of Public Health to Study Reimbursement Rates

The State Department of Public Health shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

OTHER IMPORTANT SECTIONS OF THE BUSINESS & PROFESSIONS CODE

31. Licensee or Applicant Name on Tax Delinquencies List

(a) As used in this section, "board" means any entity listed in Section 101, the entities referred to in Sections 1000 and 3600, the State Bar, the Department of Real Estate, and any other state agency that issues a license, certificate, or registration authorizing a person to engage in a business or profession.

(b) Each applicant for the issuance or renewal of a license, certificate, registration, or other means to engage in a business or profession regulated by a board who is not in compliance with a judgment or order for support shall be subject to Section 17520 of the Family Code.

(c) "Compliance with a judgment or order for support" has the meaning given in paragraph (4) of subdivision (a) of Section 17520 of the Family Code.

(d) Each licensee or applicant whose name appears on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code shall be subject to Section 494.5.

(e) Each application for a new license or renewal of a license shall indicate on the application that the law allows the State Board of Equalization and the Franchise Tax Board to share taxpayer information with a board and requires the licensee to pay his or her state tax obligation and that his or her license may be suspended if the state tax obligation is not paid.

(f) For purposes of this section, "tax obligation" means the tax imposed under, or in accordance with, Part 1 (commencing with Section 6001), Part 1.5 (commencing with Section 7200), Part 1.6 (commencing with Section 7251), Part 1.7 (commencing with Section 7280), Part 10 (commencing with Section 17001), or Part 11 (commencing with Section 23001) of Division 2 of the Revenue and Taxation Code.

40. Expert Consultant Agreement

(a) Subject to the standards described in Section 19130 of the Government Code, any board, as defined in Section 22, the State Board of Chiropractic Examiners, or the Osteopathic Medical Board of California may enter into an agreement with an expert consultant to do any of the following:

(1) Provide an expert opinion on enforcement-related matters, including providing testimony at an administrative hearing.

(2) Assist the board as a subject matter expert in examination development, examination validation, or occupational analyses.

(3) Evaluate the mental or physical health of a licensee or an applicant for a license as may be necessary to protect the public health and safety.

(b) An executed contract between a board and an expert consultant shall be exempt from the provisions of Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(c) Each board shall establish policies and procedures for the selection and use of expert consultants.

(d) Nothing in this section shall be construed to expand the scope of practice of an expert consultant providing services pursuant to this section.

[Edit. To protect and safeguard consumers and the public in this state, it is necessary that this act take effect immediately—September 26, 2011]

114.5. Applicants; Military Service Inquiry

Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

115.4. Expedited Licensure For Honorably Discharged Member of the Armed Forces

(a) Notwithstanding any other law, on and after July 1, 2016, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces of the United States and was honorably discharged.

(b) A board may adopt regulations necessary to administer this section.

115.5. Expedited Licensure Process

(a) A board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:

(1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a license from the board.

(b) A board may adopt regulations necessary to administer this section.

125.3. Recovery of Investigation and Enforcement Costs: Procedures; Proof; Enforcement

(a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licentiate that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licentiate to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(g) (1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licentiate who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licentiate who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(i) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

(k) Notwithstanding the provisions of this section, the Medical Board of California shall not request nor obtain from a physician and surgeon, investigation and prosecution costs for a disciplinary proceeding against the licensee. The board shall ensure that this subdivision is revenue neutral with regard to it and that any loss of revenue or increase in costs resulting from this subdivision is offset by an increase in the amount of the initial license fee and the biennial renewal fee, as provided in subdivision (e) of Section 2435.

125.9. Citation and Fine

(a) Except with respect to persons regulated under Chapter 11 (commencing with Section 7500), and Chapter 11.6 (commencing with Section 7590) of Division 3, any board, bureau, or commission within the department, the board created by the Chiropractic Initiative Act, and the Osteopathic Medical Board of California, may establish, by regulation, a system for the issuance to a licensee of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the board, bureau, or commission where the licensee is in violation of the applicable licensing act or any regulation adopted pursuant thereto.

(b) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the board, bureau, or commission exceed five thousand dollars (\$5,000) for each inspection or each investigation made with respect to the violation, or five thousand dollars (\$5,000) for each violation or count if the violation involves fraudulent billing submitted to an insurance company, the Medi-Cal program, or Medicare. In assessing a fine, the board, bureau, or commission shall give due consideration to the appropriateness of the amount of the fine with respect to factors such as the gravity of the violation, the good faith of the licensee, and the history of previous violations.

(4) A citation or fine assessment issued pursuant to a citation shall inform the licensee that if he or she desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board, bureau, or commission within 30 days of the date of issuance of the citation or assessment. If a hearing is not requested pursuant to this section, payment of any fine shall not constitute an admission of the violation charged. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) Failure of a licensee to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action being taken by the board, bureau, or commission. Where a citation is not contested

and a fine is not paid, the full amount of the assessed fine shall be added to the fee for renewal of the license. A license shall not be renewed without payment of the renewal fee and fine.

(c) The system may contain the following provisions:

(1) A citation may be issued without the assessment of an administrative fine.

(2) Assessment of administrative fines may be limited to only particular violations of the applicable licensing act.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the special fund of the particular board, bureau, or commission.

144.5. Authority To Receive Certified Records

Notwithstanding any other law, a board described in Section 144 may request, and is authorized to receive, from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. A local or state agency may provide those records to the board upon request.

148. Unlicensed Activity

Any board, bureau, or commission within the department may, in addition to the administrative citation system authorized by Section 125.9, also establish, by regulation, a similar system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of that board, bureau, or commission. The administrative citation system authorized by this section shall meet the requirements of Section 125.9 and may not be applied to an unlicensed person who is otherwise exempted from the provisions of the applicable licensing act. The establishment of an administrative citation system for unlicensed activity does not preclude the use of other enforcement statutes for unlicensed activities at the discretion of the board, bureau, or commission.

208. CURES Fee Assessment

(a) Beginning April 1, 2014, a Controlled Substance Utilization Review and Evaluation System (CURES) fee of six dollars (\$6) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than six dollars (\$6) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Beginning July 1, 2017, licensees issued a license that has been placed in a retired or inactive status pursuant to a statute or regulation are exempt from the CURES fee requirement in subdivision (a). This exemption shall not apply to licensees whose license has been placed in a retired or inactive status if the licensee is at any time authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Wholesalers, third-party logistics providers, nonresident wholesalers, and nonresident third-party logistics providers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(4) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(5) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the California Board of Podiatric Medicine to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

209. CURES Prescription Drug Monitoring Program; Application and Approval Process

The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that he or she is applying for licensure or renewing his or her license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to order reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

315.2 Violation of Probation; Order for Licensee to Cease Practice

(a) A board, as described in Section 315, shall order a licensee of the board to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

315.4. Order Clinical Diagnostic Evaluation for Licensee

(a) A board, as described in Section 315, may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

460. Licensed Department of Consumer Affairs Businesses

(a) No city, county, or city and county shall prohibit a person or group of persons, authorized by one of the agencies in the Department of Consumer Affairs or an entity established pursuant to this code by a license, certificate, or other means to engage in a particular business, from engaging in that business, occupation, or profession or any portion of that business, occupation, or profession.

(b) (1) No city, county, or city and county shall prohibit a healing arts professional licensed with the state under Division 2 (commencing with Section 500) or licensed or certified by an entity established pursuant to this code from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee.

(2) This subdivision shall not be construed to prohibit the enforcement of a local ordinance in effect prior to January 1, 2010, related to any act or procedure that falls within the professionally recognized scope of practice of a healing arts professional licensed under Division 2 (commencing with Section 500).

(c) This section shall not be construed to prevent a city, county, or city and county from adopting or enforcing any local ordinance governing zoning, business licensing, or reasonable health and safety requirements for establishments or businesses of a healing arts professional licensed under Division 2 (commencing with Section 500) or licensed or certified by an entity established under this code or a person or group of persons described in subdivision (a).

(d) Nothing in this section shall prohibit any city, county, or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purpose of covering the cost of regulation.

476. Licensure/Registration Related to Section 31

(a) Except as provided in subdivision (b), nothing in this division shall apply to the licensure or registration of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3, or pursuant to Division 9 (commencing with Section 23000) or pursuant to Chapter 5 (commencing with Section 19800) of Division 8.

(b) Section 494.5 shall apply to the licensure of persons authorized to practice law pursuant to Chapter 4 (commencing with Section 6000) of Division 3, and the licensure or registration of persons pursuant to Chapter 5 (commencing with Section 19800) of Division 8 or pursuant to Division 9 (commencing with Section 23000).

480. Denial of Licenses

(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

(1) Been convicted of a crime. A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that a board is permitted to take following the establishment of a conviction may be taken 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 the provisions of Section 1203.4, 1203.4a, or 1203.41 of the Penal Code.

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

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that he or she has been convicted of a misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation developed by the board to evaluate the rehabilitation of a person when considering the denial of a license under subdivision (a) of Section 482.

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

494.5. License Shall Not be Issued, Reactivated, Reinstated, or Renewed and be Suspended if Named on Certified Tax Delinquencies List

(a) (1) Except as provided in paragraphs (2), (3), and (4), a state governmental licensing entity shall refuse to issue, reactivate, reinstate, or renew a license and shall suspend a license if a licensee's name is included on a certified list.

(2) The Department of Motor Vehicles shall suspend a license if a licensee's name is included on a certified list. Any reference in this section to the issuance, reactivation, reinstatement, renewal, or denial of a license shall not apply to the Department of Motor Vehicles.

(3) The State Bar of California may recommend to refuse to issue, reactivate, reinstate, or renew a license and may recommend to suspend a license if a licensee's name is included on a certified list. The word "may" shall be substituted for the word "shall" relating to the issuance of a temporary license, refusal to issue, reactivate, reinstate, renew, or suspend a license in this section for licenses under the jurisdiction of the California Supreme Court.

(4) The Alcoholic Beverage Control Board may refuse to issue, reactivate, reinstate, or renew a license, and may suspend a license, if a licensee's name is included on a certified list.

(b) For purposes of this section:

(1) "Certified list" means either the list provided by the State Board of Equalization or the list provided by the Franchise Tax Board of persons whose names appear on the lists of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code, as applicable.

(2) "License" includes a certificate, registration, or any other authorization to engage in a profession or occupation issued by a state governmental licensing

entity. "License" includes a driver's license issued pursuant to Chapter 1 (commencing with Section 12500) of Division 6 of the Vehicle Code.

"License" excludes a vehicle registration issued pursuant to Division 3 (commencing with Section 4000) of the Vehicle Code.

(3) "Licensee" means an individual authorized by a license to drive a motor vehicle or authorized by a license, certificate, registration, or other authorization to engage in a profession or occupation issued by a state governmental licensing entity.

(4) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420, the office of the Attorney General, the Department of Insurance, the Department of Motor Vehicles, the State Bar of California, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing an individual to engage in a profession or occupation, including any certificate, business or occupational license, or permit or license issued by the Department of Motor Vehicles or the Department of the California Highway Patrol. "State governmental licensing entity" shall not include the Contractors' State License Board.

(c) The State Board of Equalization and the Franchise Tax Board shall each submit its respective certified list to every state governmental licensing entity. The certified lists shall include the name, social security number or taxpayer identification number, and the last known address of the persons identified on the certified lists.

(d) Notwithstanding any other law, each state governmental licensing entity shall collect the social security number or the federal taxpayer identification number from all applicants for the purposes of matching the names of the certified lists provided by the State Board of Equalization and the Franchise Tax Board to applicants and licensees.

(e) (1) Each state governmental licensing entity shall determine whether an applicant or licensee is on the most recent certified list provided by the State Board of Equalization and the Franchise Tax Board.

(2) If an applicant or licensee is on either of the certified lists, the state governmental licensing entity shall immediately provide a preliminary notice to the applicant or licensee of the entity's intent to suspend or withhold issuance or renewal of the license. The preliminary notice shall be delivered personally or by mail to the applicant's or licensee's last known mailing address on file with the state governmental licensing entity within 30 days of receipt of the certified list. Service by mail shall be completed in accordance with Section 1013 of the Code of Civil Procedure.

(A) The state governmental licensing entity shall issue a temporary license valid for a period of 90 days to any applicant whose name is on a certified list if the applicant is otherwise eligible for a license.

(B) The 90-day time period for a temporary license shall not be extended. Only one temporary license shall be issued during a regular license term and the term of the temporary license shall coincide with the first 90 days of the regular license term. A license for the full term or the remainder of the license term may be issued or renewed only upon compliance with this section.

(C) In the event that a license is suspended or an application for a license or the renewal of a license is denied pursuant to this section, any funds paid by the applicant or licensee shall not be refunded by the state governmental licensing entity.

(f) (1) A state governmental licensing entity shall refuse to issue or shall suspend a license pursuant to this section no sooner than 90 days and no later than 120 days of the mailing of the preliminary notice described in paragraph (2) of subdivision (e), unless the state governmental licensing entity has received a release pursuant to subdivision (h). The procedures in the administrative adjudication provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the denial or suspension of, or refusal to renew, a license or the issuance of a temporary license pursuant to this section.

(2) Notwithstanding any other law, if a board, bureau, or commission listed in Section 101, other than the Contractors' State License Board, fails to take action in accordance with this section, the Department of Consumer Affairs shall issue a temporary license or suspend or refuse to issue, reactivate, reinstate, or renew a license, as appropriate.

(g) Notices shall be developed by each state governmental licensing entity. For an applicant or licensee on the State Board of Equalization's certified list, the notice shall include the address and telephone number of the State Board of Equalization, and shall emphasize the necessity of obtaining a release from the State Board of Equalization as a condition for the issuance, renewal, or continued valid status of a license or licenses. For an applicant or licensee on the Franchise Tax Board's certified list, the notice shall include the address and telephone number of the Franchise Tax Board, and shall emphasize the necessity of obtaining a release from the Franchise Tax Board as a condition for the issuance, renewal, or continued valid status of a license or licenses.

(1) The notice shall inform the applicant that the state governmental licensing entity shall issue a temporary license, as provided in subparagraph (A) of paragraph (2) of subdivision (e), for 90 calendar days if the applicant is otherwise eligible and that upon expiration of that time period, the license will be denied unless the state governmental licensing entity has received a release from the State Board of Equalization or the Franchise Tax Board, whichever is applicable.

(2) The notice shall inform the licensee that any license suspended under this section will remain suspended until the state governmental licensing entity receives a release along with applications and fees, if applicable, to reinstate the license.

(3) The notice shall also inform the applicant or licensee that if an application is denied or a license is suspended pursuant to this section, any moneys paid by the applicant or licensee shall not be refunded by the state governmental licensing entity. The state governmental licensing entity shall also develop a form that the applicant or licensee shall use to request a release by the State Board of Equalization or the Franchise Tax Board. A copy of this form shall be included with every notice sent pursuant to this subdivision.

(h) If the applicant or licensee wishes to challenge the submission of his or her name on a certified list, the applicant or licensee shall make a timely written request for release to the State

Board of Equalization or the Franchise Tax Board, whichever is applicable. The State Board of Equalization or the Franchise Tax Board shall immediately send a release to the appropriate state governmental licensing entity and the applicant or licensee, if any of the following conditions are met:

(1) The applicant or licensee has complied with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, as described in Section 6832 or 19008 of the Revenue and Taxation Code, to satisfy the unpaid taxes.

(2) The applicant or licensee has submitted a request for release not later than 45 days after the applicant's or licensee's receipt of a preliminary notice described in paragraph (2) of subdivision (e), but the State Board of Equalization or the Franchise Tax Board, whichever is applicable, will be unable to complete the release review and send notice of its findings to the applicant or licensee and state governmental licensing entity within 45 days after the State Board of Equalization's or the Franchise Tax Board's receipt of the applicant's or licensee's request for release. Whenever a release is granted under this paragraph, and, notwithstanding that release, the applicable license or licenses have been suspended erroneously, the state governmental licensing entity shall reinstate the applicable licenses with retroactive effect back to the date of the erroneous suspension and that suspension shall not be reflected on any license record.

(3) The applicant or licensee is unable to pay the outstanding tax obligation due to a current financial hardship. "Financial hardship" means financial hardship as determined by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, where the applicant or licensee is unable to pay any part of the outstanding liability and the applicant or licensee is unable to qualify for an installment payment arrangement as provided for by Section 6832 or Section 19008 of the Revenue and Taxation Code. In order to establish the existence of a financial hardship, the applicant or licensee shall submit any information, including information related to reasonable business and personal expenses, requested by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, for purposes of making that determination.

(i) An applicant or licensee is required to act with diligence in responding to notices from the state governmental licensing entity and the State Board of Equalization or the Franchise Tax Board with the recognition that the temporary license will lapse or the license suspension will go into effect after 90 days and that the State Board of Equalization or the Franchise Tax Board must have time to act within that period. An applicant's or licensee's delay in acting, without good cause, which directly results in the inability of the State Board of Equalization or the Franchise Tax Board, whichever is applicable, to complete a review of the applicant's or licensee's request for release shall not constitute the diligence required under this section which would justify the issuance of a release. An applicant or licensee shall have the burden of establishing that he

or she diligently responded to notices from the state governmental licensing entity or the State Board of Equalization or the Franchise Tax Board and that any delay was not without good cause.

(j) The State Board of Equalization or the Franchise Tax Board shall create release forms for use pursuant to this section. When the applicant or licensee has complied with the tax obligation by payment of the unpaid taxes, or entry into an installment payment agreement, or establishing the existence of a current financial hardship as defined in paragraph (3) of subdivision (h), the State

Board of Equalization or the Franchise Tax Board, whichever is applicable, shall mail a release form to the applicant or licensee and provide a release to the appropriate state governmental licensing entity. Any state governmental licensing entity that has received a release from the State Board of Equalization and the Franchise Tax Board pursuant to this subdivision shall process the release within five business days of its receipt. If the State Board of Equalization or the Franchise Tax Board determines subsequent to the issuance of a release that the licensee has not complied with their installment payment agreement, the State Board of Equalization or the Franchise Tax Board, whichever is applicable, shall notify the state governmental licensing entity and the licensee in a format prescribed by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, that the licensee is not in compliance and the release shall be rescinded. The State Board of Equalization and the Franchise Tax Board may, when it is economically feasible for the state governmental licensing entity to develop an automated process for complying with this subdivision, notify the state governmental licensing entity in a manner prescribed by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, that the licensee has not complied with the installment payment agreement. Upon receipt of this notice, the state governmental licensing entity shall immediately notify the licensee on a form prescribed by the state governmental licensing entity that the licensee's license will be suspended on a specific date, and this date shall be no longer than 30 days from the date the form is mailed. The licensee shall be further notified that the license will remain suspended until a new release is issued in accordance with this subdivision.

(k) The State Board of Equalization and the Franchise Tax Board may enter into interagency agreements with the state governmental licensing entities necessary to implement this section.

(l) Notwithstanding any other law, a state governmental licensing entity, with the approval of the appropriate department director or governing body, may impose a fee on a licensee whose license has been suspended pursuant to this section. The fee shall not exceed the amount necessary for the state governmental licensing entity to cover its costs in carrying out the provisions of this section. Fees imposed pursuant to this section shall be deposited in the fund in which other fees imposed by the state governmental licensing entity are deposited and shall be available to that entity upon appropriation in the annual Budget Act.

(m) The process described in subdivision (h) shall constitute the sole administrative remedy for contesting the issuance of a temporary license or the denial or suspension of a license under this section.

(n) Any state governmental licensing entity receiving an inquiry as to the licensed status of an applicant or licensee who has had a license denied or suspended under this section or who has been granted a temporary license under this section shall respond that the license was denied or suspended or the temporary license was issued only because the licensee appeared on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code. Information collected pursuant to this section by any state agency, board, or department shall be subject to the Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code). Any state governmental licensing entity that discloses on its Internet Web site or other publication that the licensee has had a license denied or suspended under this section or has been granted a temporary license under this section shall prominently disclose, in bold and adjacent to the information regarding the status of the license, that the only reason the license was denied, suspended, or temporarily issued is because the licensee failed to pay taxes.

(o) Any rules and regulations issued pursuant to this section by any state agency, board, or department may be adopted as emergency regulations in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

The adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, and safety, or general welfare. The regulations shall become effective immediately upon filing with the Secretary of State.

(p) The State Board of Equalization, the Franchise Tax Board, and state governmental licensing entities, as appropriate, shall adopt regulations as necessary to implement this section.

(q) (1) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any information obtained from the State Board of Equalization or the Franchise Tax Board, pursuant to this section, except to inform the public of the denial, refusal to renew, or suspension of a license or the issuance of a temporary license pursuant to this section. The release or other use of information received by a state governmental licensing entity pursuant to this section, except as authorized by this section, is punishable as a misdemeanor. This subdivision may not be interpreted to prevent the State Bar of California from filing a request with the Supreme Court of California to suspend a member of the bar pursuant to this section.

(2) A suspension of, or refusal to renew, a license or issuance of a temporary license pursuant to this section does not constitute denial or discipline of a licensee for purposes of any reporting requirements to the National Practitioner

Data Bank and shall not be reported to the National Practitioner Data Bank or the Healthcare Integrity and Protection Data Bank.

(3) Upon release from the certified list, the suspension or revocation of the applicant's or licensee's license shall be purged from the state governmental licensing entity's Internet Web site or other publication within three business days. This paragraph shall not apply to the State Bar of California.

(r) If any provision of this section or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

(s) All rights to review afforded by this section to an applicant shall also be afforded to a licensee.

(t) Unless otherwise provided in this section, the policies, practices, and procedures of a state governmental licensing entity with respect to license suspensions under this section shall be the same as those applicable with respect to suspensions pursuant to Section 17520 of the Family Code.

(u) No provision of this section shall be interpreted to allow a court to review and prevent the collection of taxes prior to the payment of those taxes in violation of the California Constitution.

(v) This section shall apply to any licensee whose name appears on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code on or after July 1, 2012.

650. Rebates or Discounts for Referral Prohibited

(a) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

(c) The offer, delivery, receipt, or acceptance of any consideration between a federally qualified health center, as defined in Section 1396d(l)(2)(B) of Title 42 of the United States Code, and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to the health center entity pursuant to a contract, lease, grant, loan, or other agreement, if that agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a

medically underserved population served by the health center, shall be permitted only to the extent sanctioned or permitted by federal law.

(d) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2 of this code, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

(e) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2 of this code, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, as described in subsections (x) and (y) of Section 1001.952 of Title 42 of the Code of Federal Regulations, as amended October 4, 2007, as published in the Federal Register (72 Fed. Reg. 56632 and 56644), and subsequently amended versions.

(f) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Public Health under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(g) Notwithstanding the other subdivisions of this section or any other provision of law, the payment or receipt of consideration for advertising, wherein a licensee offers or sells services through a third-party advertiser, shall not constitute a referral of patients when the third-party advertiser does not itself recommend, endorse, or otherwise select a licensee. The fee paid to the third-party advertiser shall be commensurate with the service provided by the third-party advertiser. If the licensee determines, after consultation with the purchaser of the service, that the service provided by the licensee is not appropriate for the purchaser or if the purchaser elects not to receive the service for any reason and requests a refund, the purchaser shall receive a refund of the full purchase price as determined by the terms of the advertising service agreement between the third-party advertiser and the licensee. The licensee shall disclose in the advertisement that a consultation is required and that the purchaser will receive a refund if not eligible to receive the service. This subdivision shall not apply to basic health care services, as defined in subdivision (b) of Section 1345 of the Health and Safety Code, or essential health benefits, as defined in Section 1367.005 of the Health and Safety Code and Section 10112.27 of the Insurance Code. The entity that provides the advertising shall be able to demonstrate that the licensee consented in writing to the requirements of this subdivision. A third-party advertiser shall make

available to prospective purchasers advertisements for services of all licensees then advertising through the third-party advertiser in the applicable geographic region. In any advertisement offering a discount price for a service, the licensee shall also disclose the regular, nondiscounted price for that service.

(h) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in a county jail for not more than one year, or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding fifty thousand dollars (\$50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by that imprisonment and a fine of fifty thousand dollars (\$50,000).

650.1. Lease Prohibition –Hospitals or Prescribers

(a) Any amount payable to any hospital, as defined in Section 4028, or any person or corporation prohibited from pharmacy permit ownership by subdivision (a) of Section 4111 under any rental, lease or service arrangement with respect to the furnishing or supply of pharmaceutical services and products, which is determined as a percentage, fraction, or portion of (1) the charges to patients or of (2) any measure of hospital or pharmacy revenue or cost, for pharmaceuticals and pharmaceutical services is prohibited.

(b) Any lease or rental arrangement existing on the effective date of this section shall be in full compliance with subdivision (a) by January 1, 1986.

(c) Any lease or rental agreement entered into prior to January 1, 1980, that extends beyond the effective date of this section shall be construed to be in compliance with this section until its expiration or the expiration of any option which is contained in any such lease or rental agreement provided that the lease or rental agreement contains provisions which limit pharmacy charges to the amounts not in excess of the prevailing charges in similar hospitals in the general geographic area.

(d) The California State Board of Pharmacy, the Medical Board of California, and the State Department of Health Services shall enforce this section and may require information from any person as is necessary for the enforcement of this section. It shall be the duty of the licensees of the respective regulatory agencies to produce the requisite evidence to show compliance with this section. Violations of this section shall be deemed to be the mutual responsibility of both lessee and lessor, and shall be grounds for disciplinary action or other sanctions against both.

651. Professional Advertising Requirements

(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail,

television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

- (1) Contains a misrepresentation of fact.
- (2) Is likely to mislead or deceive because of a failure to disclose material facts.
- (3) (A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

(B) Use of any photograph or other image of a model without clearly stating in a prominent location in easily readable type the fact that the photograph or image is of a model is a violation of subdivision (a). For purposes of this paragraph, a model is anyone other than an actual patient, who has undergone the procedure being advertised, of the licensee who is advertising for his or her services.

(C) Use of any photograph or other image of an actual patient that depicts or purports to depict the results of any procedure, or presents "before" and "after" views of a patient, without specifying in a prominent location in easily readable type size what procedures were performed on that patient is a violation of subdivision (a). Any "before" and "after" views (i) shall be comparable in presentation so that the results are not distorted by favorable poses, lighting, or other features of presentation, and (ii) shall contain a statement that the same "before" and "after" results may not occur for all patients.

(4) Relates to fees, other than a standard consultation fee or a range of fees for specific types of services, without fully and specifically disclosing all variables and other material factors.

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

(c) Any price advertisement shall be exact, without the use of phrases, including, but not limited to, "as low as," "and up," "lowest prices," or words or phrases of similar import. Any advertisement that refers to services, or costs for services, and that uses words of comparison shall be based on verifiable data substantiating the comparison. Any person so advertising shall be prepared to provide information sufficient to establish the accuracy of that comparison. Price advertising shall not be fraudulent, deceitful, or misleading, including statements or advertisements of bait, discount, premiums, gifts, or

any statements of a similar nature. In connection with price advertising, the price for each product or service shall be clearly identifiable. The price advertised for products shall include charges for any related professional services, including dispensing and fitting services, unless the advertisement specifically and clearly indicates otherwise.

(d) Any person so licensed shall not compensate or give anything of value to a representative of the press, radio, television, or other communication medium in anticipation of, or in return for, professional publicity unless the fact of compensation is made known in that publicity.

(e) Any person so licensed may not use any professional card, professional announcement card, office sign, letterhead, telephone directory listing, medical list, medical directory listing, or a similar professional notice or device if it includes a statement or claim that is false, fraudulent, misleading, or deceptive within the meaning of subdivision (b).

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

(h) Advertising by any person so licensed may include the following:

(1) A statement of the name of the practitioner.

(2) A statement of addresses and telephone numbers of the offices maintained by the practitioner.

(3) A statement of office hours regularly maintained by the practitioner.

(4) A statement of languages, other than English, fluently spoken by the practitioner or a person in the practitioner's office.

(5) (A) A statement that the practitioner is certified by a private or public board or agency or a statement that the practitioner limits his or her practice to specific fields.

(i) For the purposes of this section, a dentist licensed under Chapter 4 (commencing with Section 1600) may not hold himself or herself out as a specialist, or advertise membership in or specialty recognition by an accrediting organization, unless the practitioner has completed a specialty education program approved by the American Dental Association and the Commission on Dental Accreditation, is eligible for examination by a national specialty board recognized by the American Dental Association, or is a diplomate of a national specialty board recognized by the American Dental Association.

(ii) A dentist licensed under Chapter 4 (commencing with Section 1600) shall not represent to the public or advertise accreditation either in a specialty area of practice or by a board not meeting the requirements of clause (i) unless the dentist has attained membership in or otherwise been credentialed by an accrediting organization that is recognized by the board as a bona fide organization for that area of dental practice. In order to be recognized by the board as a bona fide accrediting organization for a specific area of dental practice other than a specialty area of dentistry authorized under clause (i), the

organization shall condition membership or credentialing of its members upon all of the following:

(I) Successful completion of a formal, full-time advanced education program that is affiliated with or sponsored by a university based dental school and is beyond the dental degree at a graduate or postgraduate level.

(II) Prior didactic training and clinical experience in the specific area of dentistry that is greater than that of other dentists.

(III) Successful completion of oral and written examinations based on psychometric principles.

(iii) Notwithstanding the requirements of clauses (i) and (ii), a dentist who lacks membership in or certification, diplomate status, other similar credentials, or completed advanced training approved as bona fide either by an American Dental Association recognized accrediting organization or by the board, may announce a practice emphasis in any other area of dental practice only if the dentist incorporates in capital letters or some other manner clearly distinguishable from the rest of the announcement, solicitation, or advertisement that he or she is a general dentist.

(iv) A statement of certification by a practitioner licensed under Chapter 7 (commencing with Section 3000) shall only include a statement that he or she is certified or eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board.

(B) A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she limits his or her practice to specific fields, but shall not include a statement that he or she is certified or eligible for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, unless that board or association is (i) an American Board of Medical Specialties member board, (ii) a board or association with equivalent requirements approved by that physician and surgeon's licensing board, or (iii) a board or association with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in that specialty or subspecialty. A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification, unless the physician and surgeon is also licensed under Chapter 4 (commencing with Section 1600) and the use of the term "board certified" in reference to that certification is in accordance with subparagraph (A). A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the Medical Board of California, for certifying medical doctors and other

health care professionals that is based on the applicant's education, training, and experience.

For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is an American Board of Medical Specialties member board, an organization with equivalent requirements approved by a physician and surgeon's licensing board, or an organization with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in a specialty or subspecialty. The Medical Board of California shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph. The fee shall not exceed the cost of administering this subparagraph. Notwithstanding Section 2 of Chapter 1660 of the Statutes of 1990, this subparagraph shall become operative July 1, 1993. However, an administrative agency or accrediting organization may take any action contemplated by this subparagraph relating to the establishment or approval of specialist requirements on and after January 1, 1991.

(C) A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she is certified or eligible or qualified for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, if that board or association meets one of the following requirements:

- (i) is approved by the Council on Podiatric Medical Education,
- (ii) is a board or association with equivalent requirements approved by the California Board of Podiatric Medicine, or (iii) is a board or association with the Council on Podiatric Medical Education approved postgraduate training programs that provide training in podiatric medicine and podiatric surgery. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the California Board of Podiatric Medicine, for certifying doctors of podiatric medicine that is based on the applicant's education, training, and experience. For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is a Council on Podiatric Medical Education approved board, an organization with equivalent requirements approved by the California Board of Podiatric Medicine, or an organization with a Council on Podiatric Medical

Education approved postgraduate training program that provides training in podiatric medicine and podiatric surgery.

The California Board of Podiatric Medicine shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph, to be deposited in the State Treasury in the Podiatry Fund, pursuant to Section 2499. The fee shall not exceed the cost of administering this subparagraph.

(6) A statement that the practitioner provides services under a specified private or public insurance plan or health care plan.

(7) A statement of names of schools and postgraduate clinical training programs from which the practitioner has graduated, together with the degrees received.

(8) A statement of publications authored by the practitioner.

(9) A statement of teaching positions currently or formerly held by the practitioner, together with pertinent dates.

(10) A statement of his or her affiliations with hospitals or clinics.

(11) A statement of the charges or fees for services or commodities offered by the practitioner.

(12) A statement that the practitioner regularly accepts installment payments of fees.

(13) Otherwise lawful images of a practitioner, his or her physical facilities, or of a commodity to be advertised.

(14) A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of commodities advertised.

(15) An advertisement of a registered dispensing optician may include statements in addition to those specified in paragraphs (1) to (14), inclusive, provided that any statement shall not violate subdivision (a), (b), (c), or (e) or any other section of this code.

(16) A statement, or statements, providing public health information encouraging preventative or corrective care.

(17) Any other item of factual information that is not false, fraudulent, misleading, or likely to deceive.

(i) Each of the healing arts boards and examining committees within Division 2 shall adopt appropriate regulations to enforce this section in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Each of the healing arts boards and committees and examining committees within Division 2 shall, by regulation, define those efficacious services to be advertised by businesses or professions under their jurisdiction for the purpose of determining whether advertisements are false or misleading. Until a definition for that service has been issued, no advertisement for that service shall be disseminated. However, if a definition of a service has not been issued by a board or committee within 120 days of receipt of a request from a licensee, all those holding the license may advertise the service. Those boards and committees shall adopt or modify regulations defining what services may be advertised, the manner in which defined services may be advertised, and restricting advertising that would promote the inappropriate or excessive use of

health services or commodities. A board or committee shall not, by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

(j) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

(k) A physician and surgeon or doctor of podiatric medicine licensed pursuant to Chapter 5 (commencing with Section 2000) by the Medical Board of California who knowingly and intentionally violates this section may be cited and assessed an administrative fine not to exceed ten thousand dollars (\$10,000) per event. Section 125.9 shall govern the issuance of this citation and fine except that the fine limitations prescribed in paragraph (3) of subdivision (b) of Section 125.9 shall not apply to a fine under this subdivision.

652. Violation as Unprofessional Conduct

Violation of this article in the case of a licensed person constitutes unprofessional conduct and grounds for suspension or revocation of his or her license by the board by whom he or she is licensed, or if a license has been issued in connection with a place of business, then for the suspension or revocation of the place of business in connection with which the violation occurs. The proceedings for suspension or revocation shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and each board shall have all the powers granted therein. However, in the case of a licensee of the State Department of Health Services, the proceedings shall be conducted in accordance with Section 110171 of the Health and Safety Code. In addition, any violation constitutes a misdemeanor as to any and all persons offering, delivering, receiving, accepting, or participating in any rebate, refund, commission, preference, patronage dividend, unearned discount, or consideration, whether or not licensed under this division, and is punishable by imprisonment in the county jail not exceeding six months, by a fine not exceeding two thousand five hundred dollars (\$2,500), or by both the imprisonment and fine.

652.5. Violation as Misdemeanor

Except as otherwise provided in this article, any violation of this article constitutes a misdemeanor as to any and all persons, whether or not licensed under this division, and is punishable by imprisonment in the county jail not

exceeding six months, or by a fine not exceeding two thousand five hundred dollars (\$2,500), or by both the imprisonment and fine.

733. Dispensing Prescription Drugs and Devices

(a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives described in Section 4052.3.

- (e) This section imposes no duty on a licensee to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licensee or payment of any required copayment by the patient.
- (f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

901. Authorization for Out-of-State Health Practitioner to Participate in Sponsored Events in California

- (a) For purposes of this section, the following provisions apply:
- (1) "Board" means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.
- (2) "Health care practitioner" means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.
- (3) "Sponsored event" means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.
- (4) "Sponsoring entity" means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.
- (5) "Uninsured or underinsured person" means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.
- (b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:
- (1) Prior to providing those services, he or she does all of the following:
- (A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.
- (B) Satisfies the following requirements:
- (i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under

Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

(A) To uninsured or underinsured persons.

(B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.

(C) In association with a sponsoring entity that complies with subdivision (d).

(D) Without charge to the recipient or to a third party on behalf of the recipient.

(c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to comply with this section or for any act that would be grounds for denial of an application for licensure.

(d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:

(1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:

(A) The name of the sponsoring entity.

(B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.

(C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).

(D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).

(E) Any additional information required by the board.

(2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.

(e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.

(f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description

of the care provided, along with a listing of the health care practitioners who participated in providing that care.

(g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.

(h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.

(i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.

(j) (1) The board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.

(2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

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

(l) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

17500. False or Misleading Statements, Generally

It is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services, professional or otherwise, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services, professional or otherwise, or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or for any person, firm, or corporation to so make or disseminate or cause to be so made or disseminated any such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, so advertised at the price stated therein, or as so advertised. Any violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars (\$2,500), or by both that imprisonment and fine.

CALIFORNIA CODE OF REGULATIONS

DIVISION 17, TITLE 16

Article 1. General Provisions

Section

- 1702 Pharmacist Renewal Requirements
- 1703. Delegation of Certain Functions
- 1704. Change of Address
- 1705. Notification of Bankruptcy, Receivership or Liquidation
- 1706. Words of Similar Import
- 1706.1. Permit Processing Times
- 1706.2. Abandonment of Application Files
- 1706.5. Experimental Programs

Article 2. Pharmacies

Section

- 1707. Waiver Requirements for Off-Site Storage of Records
- 1707.1. Duty to Maintain Medication Profiles (Patient Medication Records)
- 1707.2. Duty to Consult
- 1707.3. Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery
- 1707.4. Procedures for Refill Pharmacies
- 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements
- 1707.6. Notice to Consumers
- 1708.2. Discontinuance of Business
- 1708.3. Radioactive Drugs
- 1708.4. Pharmacist Handling Radioactive Drugs
- 1708.5. Pharmacy Furnishing Radioactive Drugs
- 1709. Names of Owners and Pharmacist-in-Charge
- 1709.1. Designation of Pharmacist-in-Charge
- 1710. Hospital Pharmacy
- 1711. Quality Assurance Programs
- 1712. Use of Pharmacist Identifiers
- 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy
- 1714. Operational Standards and Security
- 1714.1. Pharmacy Operations during Temporary Absence of a Pharmacist
- 1714.5. Dangerous Drugs and Devices Exempt from Provisions of Chapter 9, Division 2 of the Business and Professions Code
- 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
- 1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions
- 1715.6. Reporting Drug Loss
- 1716. Variation from Prescriptions
- 1717. Pharmacy Practice
- 1717.1. Common Electronic Files
- 1717.3. Preprinted, Multiple Checkoff Prescription Blanks

Section

- 1717.4. Electronic Transmission of Prescriptions
- 1718. Current Inventory Defined
- 1718.1 Manufacturer's Expiration Date

Article 3. Pharmacist Candidates**Section**

- 1719. Recognized Schools of Pharmacy
- 1720. Application for Pharmacist Examination and Licensure
- 1720.1. Graduates of Foreign Pharmacy Schools
- 1721. Dishonest Conduct during Examination
- 1723.1. Confidentiality of Examination Questions
- 1724. Passing Grade in Pharmacist Examination
- 1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts
- 1726. Supervision of Intern Pharmacists
- 1727.1 Intern Address Not Available on Internet
- 1727.2 Requirements for Pharmacist Intern
- 1728. Requirements for Examination

Article 3.5. Advanced Practice Pharmacist**Section**

- 1730. Acceptable Certification Programs
- 1730.1. Application Requirements for Advanced Practice Pharmacist Licensure
- 1730.2. Certification Programs
- 1731. Experimental Programs

Article 4. Continuing Education**Section**

- 1732. Definitions
- 1732.05. Accreditation Agencies for Continuing Education
- 1732.1. Requirements for Accredited Providers
- 1732.2. Board Accredited Continuing Education
- 1732.3. Requirements for Continuing Education Courses
- 1732.4. Provider Audit Requirements
- 1732.5. Renewal Requirements for Pharmacist
- 1732.6. Exemptions
- 1732.7. Complaint Mechanism

Article 4.5 Compounding**Section**

- 1735. Compounding in Licensed Pharmacies
- 1735.1. Compounding Definitions
- 1735.2. Compounding Limitations and Requirements; Self -Assessment
- 1735.3. Recordkeeping of Compounded Drug Preparations
- 1735.4. Labeling of Compounded Drug Preparations
- 1735.5. Compounding Policies and Procedures
- 1735.6. Compounding Facilities and Equipment

Section

- 1735.7. Training of Compounding Staff
- 1735.8. Compounding Quality Assurance

Article 5. Dangerous Drugs**Section**

- 1744. Drug Warnings
- 1745. Partial Filling of Schedule II Prescriptions
- 1746. Emergency Contraception
- 1746.1. Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception
- 1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products
- 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride
- 1746.4. Pharmacists Initiating and Administering Vaccines

Article 6. Fees**Section**

- 1749. Fee Schedule

Article 7. Sterile Compounding**Section**

- 1751. Sterile Compounding; Compounding Area; Self-Assessment
- 1751.1. Sterile Compounding Recordkeeping Requirements
- 1751.2. Sterile Compounding Labeling Requirements
- 1751.3. Sterile Compounding Policies and Procedures
- 1751.4. Facility and Equipment Standards for Sterile Compounding
- 1751.5. Sterile Compounding Attire
- 1751.6. Sterile Compounding Consultation; Training of Sterile Compounding Staff
- 1751.7. Sterile Compounding Quality Assurance and Process Validation
- 1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations
- 1751.9. Single-Dose and Multi-Dose Containers; Limitations on Use
- 1751.10. Sterile Compounding Reference Materials

Article 7.5. Furnishing for Home Administrations**Section**

- 1752. Furnishing to Parenteral Patient at Home
- 1753. Furnishing to Home Health Agencies and Licensed Hospices
- 1754. Obligations of a Pharmacy Furnishing Portable Containers

Article 8. Prohibitions and Discipline**Section**

- 1760. Disciplinary Guidelines
- 1761. Erroneous or Uncertain Prescriptions
- 1764. Unauthorized Disclosure of Prescriptions
- 1765. Commissions, Gratuities, and Rebates
- 1766. False or Misleading Advertising
- 1768. Denial of Application - Reapplication
- 1769. Criteria for Rehabilitation

Section

- 1770. Substantial Relationship Criteria
- 1771. Posting of Notice of Suspension
- 1772. Disciplinary Condition of Suspension
- 1773. Disciplinary Conditions of Probation of Pharmacist
- 1773.5 Ethics Course Required as Condition of Probation
- 1774. Disciplinary Conditions of Probation of Permit

Article 9. Citations and Fines**Section**

- 1775. Issuing Citations
- 1775.1 Amount of Fines
- 1775.2. Factors Considered
- 1775.3. Compliance with Orders of Abatement
- 1775.4. Contested Citations

Article 10. Wholesalers**Section**

- 1780. Minimum Standards for Wholesalers
- 1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers
- 1781. Exemption Certificate
- 1782. Reporting Sales of Drugs Subject to Abuse
- 1783. Manufacturer or Wholesaler Furnishing Drugs or Devices
- 1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge

Article 10.1. Home Dialysis Drugs and Devices**Section**

- 1787. Authorization to Distribute Hemodialysis Drugs and Devices
- 1790. Assembling and Packaging
- 1791. Labeling
- 1792. Receipt for Shipment

Article 11. Ancillary Personnel**Section**

- 1793. Definitions
- 1793.1. Duties of a Pharmacist
- 1793.2. Duties of a Pharmacy Technician
- 1793.3. Other Non-Licensed Pharmacy Personnel
- 1793.5. Pharmacy Technician Application
- 1793.6. Training Courses Specified by the Board
- 1793.7. Requirements for Pharmacies Employing Pharmacy Technicians
- 1793.8. Technicians in Hospitals with Clinical Pharmacy Programs

CALIFORNIA CODE OF REGULATIONS

DIVISION 17, TITLE 16

Article 1. General Provisions

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's renewal date that occurs on or after December 7, 2010.

(1) A pharmacists shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprint system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

1703. Delegation of Certain Functions

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements

of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; and issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

1704. Change of Address

Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4100, Business and Professions Code.

1705. Notification of Bankruptcy, Receivership or Liquidation

Any pharmacy, wholesaler, or manufacturer who makes any assignment for the benefit of creditors or enters into any creditor compromise arrangement, or who files a petition in bankruptcy, or who has a receiver appointed, or who enters into any liquidation or other arrangement which may result in the sale or transfer of drugs, devices or appliances which are required to be sold by a registered pharmacist or other licensee, shall notify the Board immediately in writing of such fact, and shall set forth the following information, if known:

- (a) Date of sale or transfer of such drugs, devices or appliances;
- (b) Name and address of purchaser;
- (c) Inventory of dangerous drugs and devices showing their disposition;
- (d) Location of records of manufacture, sale, purchase, and disposition of dangerous drugs and devices.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4024, 4080, 4081 and 4332, Business and Professions Code.

1706 Words of Similar Import

The words "Prescription," "Prescription Service," "Medication," "Prescribed Medication," and "Medicinals" are words of similar or like import to those enumerated in Section 4343, Business and Professions Code.