California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

LEGISLATION AND REGULATION COMMITTEE

Greg Lippe, CPA, Chairperson, Public Member
Lavanza Butler, Vice-Chairperson, Licensee Member
Victor Law, Licensee Member
Valerie Munoz, Public Member
Albert Wong, PharmD, Licensee Member

The committee will be meeting immediately before the Board Meeting. An update on the committee's action will be provided during the board meeting.

LEGISLATION REPORT

The second of the two-year legislative cycle ended on September 30, 2016, with the Governor taking action on the enrolled legislative proposals. Below is a brief summary of proposals and the outcomes of measures that were either board-sponsored or that impact the board's jurisdiction. Copies of the chaptered versions of each bill are provided as Attachments.

a. Board Sunset Legislation

Attachment 1

1. <u>SB 1193 (Hill, Chapter 484, Statutes of 2016) California State Board of Pharmacy</u>
   This measure includes several important changes to pharmacy law including:
   - extends the operations of the California Board of Pharmacy and the board's authority to appoint an executive officer until January 1, 2021,
   - establishes the framework for the licensure of outsourcing facilities,
   - authorizes the board to synchronize license renewal dates and aggregate fees for clinics,
   - authorizes the board to issue a temporary permit for specified licenses,
   - repeals obsolete provisions related to electronic data transmission prescriptions in the Health and Safety Code,
   - authorizes the board to issue a cease and desist order for unlicensed activity violations,
   - establishes registration requirements for automated drug delivery systems, and
   - makes other technical changes.

2. <u>SB 1039 (Hill, Chapter 799, Statutes of 2016) Professions and Vocations</u>
   This measure sets forth a new fee schedule, which is needed to sustain board operations.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Attachment 2

1. AB 1069 (Gordon, Chapter 316, Statutes of 2016) Prescription Drugs: Collection and Distribution Program
   As enacted, this measure allows a pharmacy to repackage donated medications for dispensing to indigent patients if such repackaging is performed and dispensed through a dedicated pharmacy. In its support of this measure, the board noted that a dedicated pharmacy model within a county to facilitate the redistribution of donated medications to patients is consistent with the training and functions of a pharmacist and also provides important safeguards.

2. AB 1114 (Eggman, Chapter 602, Statutes of 2016) Medi-Cal: Pharmacist Services
   This measure establishes the process for a pharmacist to be reimbursed for specified services provided as a benefit under Medi-Cal. Such services include furnishing naloxone, furnishing travel medication, furnishing self-administered hormonal contraception, initiating and administering immunizations, and providing tobacco cessation counseling and furnishing of nicotine replacement therapy. As an urgency measure, the provisions of the bill went into effect on September 25, 2016.

3. AB 1386 (Low, Chapter 374, Statutes of 2016) Emergency Medical Care: Epinephrine Auto-Injectors
   The measure authorizes a pharmacy to furnish epinephrine auto-injectors to authorized entities. The board supported this measure and noted that provisions are consistent with the practice of pharmacy, consistent with the roles and responsibilities of a pharmacist, and are important to ensure ready access to this lifesaving medication when necessary.

4. AB 1748 (Mayes, Chapter 557, Statutes of 2016) Pupils: Pupil Health: Opioid Antagonist
   This measure authorizes a pharmacy to furnish naloxone hydrochloride or other opioid antagonist to a school district, county office of education or charter school under certain conditions. The board strongly supported this measure and noted that the furnishing of such medications as a live saving measure to prevent death from an opioid overdose. This measure is consistent with the board's efforts in this area to ensure ready access to this medication.

5. SB 482 (Lara, Chapter 708, Statutes of 2016) Controlled Substances: CURES Database
   This measure requires a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II, III or IV medication for the first time and at least every four months. The bill also limits the dispensing of a controlled substance in specified settings to either a 5- or 7-day supply. The board supported this measure and noted that CURES provides point-of-care system access to California's prescription drug monitoring program for pharmacists and

prescribers, which is a valuable tool to identify potential drug-seeking behaviors, as well as potential drug diversion.

6. SB 952 (Anderson, Chapter 150, Statutes of 2016) Pharmacy Technicians: Licensure Requirements
   This bill modified licensure requirements for pharmacy technicians by expanding the certification requirement to also include other agencies as a pathway to licensure. The board supported this measure.

7. SB 999 (Pavley, Chapter 499, Statues of 2016) Health Care Coverage: Contraceptives: Annual Supply
   This bill authorizes a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity. The measure also requires a health care service plan or health insurance policy, on or after January 1, 2017, to cover a 12-month supply of a self-administered hormonal contraception dispensed at one time by a prescriber or dispenser.

8. SB 1229 (Jackson, Chapter 238, Statutes of 2016) Pharmacies: Secure Drug Take-Back Bins
   This bill encourages good-faith participation of authorized entities to provide secure drug take-back bins to provide consumers with a safe disposal option for unused pharmaceuticals. The board supported this measure as it serves to compliment the board's proposed regulations. There are a few areas of the measure that expand beyond the board's requirements. Upon approval of the board's regulation, an advisory will be provided to licensees detailing the requirements and highlighting the board's additional requirements.

Statutory changes to Pharmacy Law will be included in the next issue of *The Script* that should be released at the end of the year. In the interim, **Attachment 3** includes the statutory changes that take effect January 1, 2017, unless otherwise specified. This information will be posted on our website to assist licensees.

c. Legislative Items for Future Meeting

The committee may discuss other items of legislation in sufficient detail to determine whether such items should be on a future agenda to discuss such items pursuant to Government Code section 11125.4.

REGULATION REPORT

a. Board Adopted – Approved by the Office of Administrative Law

1. Regulations to Add Title 16 CCR section 1730.2 Related to Advanced Practice Pharmacists – Certification Programs

   In December 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1730.2, establishing the certification program criteria for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. Pursuant to the Administrative Procedure Act (APA), following review and approval by Agency, the rulemaking was submitted to the Office of Administrative Law (OAL) for final review on June 29, 2016, and they approved the rulemaking on August 10, 2016 with an immediate effective date.

   A copy of the adopted text is provided in **Attachment 4**.

2. Regulations to Add Title 16 CCR section 1746.4 Related to Immunizations (Vaccinations)

   In July 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1746.4 to specify the requirements for a pharmacist to administer vaccinations. On July 1, 2016, the board adopted the final regulation text. Pursuant to the APA, following review and approval by Agency, the rulemaking was submitted to OAL for final review on July 14, 2016, and they approved the rulemaking on August 25, 2016, with an immediate effective date.

   A copy of the adopted text is provided in **Attachment 5**.

3. Regulations to Amend Title 16 CCR sections 1735 and 1751 et seq. Related to Compounding

   In May 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1735 and 1751 et seq., related to compounded drug preparations. On January 19, 2016, the board adopted the final regulation text. Pursuant to the APA, following review and approval by Agency, the rulemaking was submitted to OAL for final review on August 1, 2016, and they approved the rulemaking on September 13, 2016. The regulation becomes effective on January 1, 2017.

   A copy of the adopted text is provided in **Attachment 6**.

b. Board Adopted – Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law

1. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) sections 1730, 1730.1 and Amend section 1749 related to Advanced Practice Pharmacists

   In July 2015, the board initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted regulation text and the rulemaking file was submitted to OAL for review in June 2016. Because OAL expressed concerns with the file, the rulemaking was returned to the board. At the July 2016 board meeting, the board voted to modify the text to address OAL's concerns and initiated a 15-day comment period. Thereafter, at the August 2016 board meeting, the board adopted final regulation language, and resubmitted the final rulemaking file to the Department of Consumer Affairs (DCA) on September 20, 2016.

   A copy of the final adopted text is provided in **Attachment 7**.

2. Proposed Regulations to Add Title 16 CCR section 1746.5 Related to Travel Medications

   In September 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1746.5, related to the furnishing of travel medications. At the April 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the DCA for review on May 9, 2016.

   A copy of the adopted regulation text is provided in **Attachment 8**.

3. Proposed Regulations to Amend Title 16 CCR section 1760 Related to the Board's Disciplinary Guidelines

   In September 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1760 related to the board's disciplinary guidelines. At the April 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to DCA for review on August 4, 2016.

   A copy of the adopted regulation text is provided in **Attachment 9**.

4. Proposed Regulations to Amend Title 16 CCR section 1744 Related to Drug Warnings

   In April 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1744 related to drug warning labels. At the July 2016 board meeting, the board adopted the final regulation text. The rulemaking file was submitted to the DCA for review on August 17, 2016.

A copy of the adopted text is provided in **Attachment 10**.

5. Proposed Regulations to Amend Title 16 CCR section 1707.5 Related to Patient-Centered Labels

   In January 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1707.5 related to the inclusion of "generic for" on a patient-centered drug label. At the August 2016 board meeting, the board adopted final regulation text. The rulemaking file was submitted to the DCA for review on September 21, 2016.

   A copy of the adopted text is provided in **Attachment 11**.

6. Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education

   In September 2015, the board initiated a formal rulemaking to amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5 related to the board's continuing education requirements. At the September 2016 board meeting, the board adopted final regulation text. The rulemaking file was submitted to the DCA for review on October 3, 2016.

   A copy of the adopted regulation text is provided in **Attachment 12**.

c. Board Adopted – Rulemaking File Being Prepared by Staff for Submission to the Department of Consumer Affairs or the Office of Administrative Law

Proposed Regulations to Amend Title 16 CCR section 1703 Related to Delegation of Certain Functions

In October 2013, the board approved draft text to delegate to the executive officer the authority to adopt regulation changes that are deemed to be "without regulatory effect" in accordance with Title 1 CCR section 100. Thereafter, at the February 2016 board meeting, the board approved proposed text to delegate to the executive officer the authority to approve prescription drug label waivers in accordance with Business and Professions Code section 4076.5(d). The rulemaking was initiated on April 22, 2016.

At the July 2016 board meeting, following the 45-day comment period, the board adopted final regulation text. Board staff is currently compiling the rulemaking package to submit to the DCA for administrative review.

A copy of the adopted text is provided in **Attachment 13**.

d. **Board Approved to Initiate Rulemaking – Open Comment Period**

Proposed Regulations to Add Title 16 CCR section 1715.65 Related to Inventory Reconciliation Report of Controlled Substances

In July 2016, the board initiated a formal rulemaking to add Title 16 CCR section 1715.65 related to inventory reconciliation report of controlled substances. The 45-day comment period began on September 16, 2016, and concludes on October 31, 2016.

A copy of the noticed regulation language is provided in **Attachment 14**.

e. **Consideration and Discussion of Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16)**

Relevant Law

Title 16 CCR sections 1715 and 1784 requires a Pharmacist-in-Charge (PIC) and a Designated Representative-in-Charge (DRIC) to complete a self-assessment no later than July 1 of each odd-numbered year, and at other times as specified.

- Title 16 CCR section 1715 applies to the self-assessment of a pharmacy by the PIC. This regulation incorporates by reference two self-assessment forms:
  - Form 17M-13 "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment"
  - Form 17M-14 "Hospital Pharmacy Self-Assessment"

- Title 16 CCR section 1784 applies to the self-assessment of a wholesaler by the DRIC. It incorporates by reference the following self-assessment form:
  - Form 17M-26 "Wholesaler

Background

The purpose of a self-assessment is to promote compliance of businesses regulated by the board through self-examination and education. Because the self-assessments forms are a compilation of Pharmacy Law, modifications must be made on an annual basis to incorporated changes in the law that are enacted since the last revision to the self-assessment forms. Because of the mandate to have these forms completed no later than July 1, 2017 of each odd-numbered year, it is necessary to update these forms prior to July 2017.

For Committee Discussion and Consideration

During the meeting the committee will have the opportunity to review the draft regulation language and self-assessment forms that are incorporated by reference in the regulations.

Should the committee determine it appropriate, the committee may wish to recommend to the board initiation of the formal rulemaking process to amend the text of Title 16 CCR sections 1715 and 1784 and to amend the self-assessment forms incorporated by reference in those sections, as proposed; authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide a 45-day public comment period. Staff recommends that no regulation hearing be scheduled, unless one is requested pursuant to the Administrative Procedure Act.

Attachment 15 contains the proposed modifications to Title 16 CCR sections 1715 and 1784 as well as the draft self-assessment forms.

PROPOSED MEETING DATES

Provided below are the proposed meeting dates for 2017:

- January 24, 2017, immediately before the board meeting
- April 12, 2017
- June 27, 2017
- October 18, 2017

Attachment 1

Senate Bill No. 1193

CHAPTER 484

An act to amend Sections 2909.5, 2913, 2914, 2914.1, 2914.2, 2915, 2920, 2933, 4001, 4003, 4013, 4035, 4081, 4107, 4110, 4119.1, 4127, 4127.3, 4127.7, 4127.8, 4127.9, 4128.6, 4161, 4180, 4201, 4301, 4302, 4307, 4308, 4312, 4400, 4406, 4800, 4804.5, 4830, 4846.5, 4904, and 4905 of, to add Sections 2934.1, 2988.5, 4034, 4105.5, 4126.9, 4203.5, 4301.1, 4303.1, 4316, 4826.5, 4848.1, and 4853.7 to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, and to repeal Section 2947 of, the Business and Professions Code, to amend Section 13401.5 of the Corporations Code, and to amend Sections 1261.6 and 11164.5 of the Health and Safety Code, relating to healing arts.

[Approved by Governor September 22, 2016. Filed with
Secretary of State September 22, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1193, Hill. Healing arts.

(1) The Psychology Licensing Law establishes the Board of Psychology to license and regulate the practice of psychology, and authorizes the board to employ all personnel necessary to carry out that law and to employ an executive officer, as specified. These provisions are in effect only until January 1, 2017.

This bill would extend the existence of the board and the board's authorization to employ an executive officer to January 1, 2021.

The Psychology Licensing Law defines the practice of psychology as rendering or offering to render, for a fee, psychological services involving the application of psychological principles and methods, including the diagnosis, prevention, and treatment of psychological problems and emotional and mental disorders. That law prohibits unlicensed persons from practicing psychology, but authorizes unlicensed persons, including psychological assistants who meet certain requirements and do not provide psychological services to the public, except as an employee of a licensed psychologist, licensed physician, contract clinic, psychological corporation, or medical corporation, to perform limited psychological functions. That law also prohibits its provisions from being construed as restricting or preventing specified nonprofit community agency employees from carrying out activities of a psychological nature or using their official employment title, as specified, provided the employees do not render or offer to render psychological services. That law provides that a violation of any of its provisions is a misdemeanor.

This bill would recast these provisions to authorize an unlicensed person preparing for licensure as a psychologist to perform psychological functions

under certain conditions, including registration with the board as a psychological assistant and immediate supervision by a licensed psychologist or physician and surgeon who is board certified in psychiatry, as specified. The bill would prohibit a psychological assistant from providing psychological services to the public except as a supervisee. The bill would expand the prohibition on construing the Psychology Licensing Law's provisions as restricting or preventing specified activities of nonprofit community agency employees by making this prohibition contingent on the employees not rendering or offering to render psychological services to the public. By changing the definition of a crime, this bill would create a state-mandated local program.

The Psychology Licensing Law conditions the issuance of a psychology license upon an applicant having received any of certain kinds of doctorate degrees from an accredited educational institution. That law requires, with certain exceptions, the board to issue renewal licenses for psychology only to those applicants who have completed 36 hours of approved continuing education in the preceding two years. Existing law prescribes a biennial license renewal fee of not more than $500. Existing law also requires a person applying for relicensure or for reinstatement to an active license to certify under penalty of perjury that he or she is in compliance with the continuing education requirements. Existing law requires continuing education instruction to be completed within the state or be approved for credit by the American Psychological Association or its equivalent.

This bill would revise and recast the doctorate degree requirements for licensure to include, until January 1, 2020, a doctorate degree from an unaccredited institution that is approved for operation by a specified entity. The bill would replace the term "continuing education" with "continuing professional development," define "continuing professional development," require a person applying for renewal or reinstatement to certify compliance with these requirements under penalty of perjury, require continuing professional courses to be approved by organizations approved by the board, as specified, and authorize the board to grant exemptions from, or extensions for compliance with, these requirements.

This bill would authorize the board to issue a retired license to a licensed psychologist if the psychologist has applied to the board for a retired license and pays a fee of not more than $75. The bill would also prohibit the holder of a retired license from engaging in the practice of psychology in the same manner as an active licensee. Because a violation of this prohibition would be a crime, the bill would impose a state-mandated local program.

Existing law authorizes the board to appoint qualified persons to give the whole or any portion of any examination provided for in the law, to be designated as commissioners on examination.

This bill would repeal this authorization.

This bill would authorize the board to post on its Internet Web site the prescribed information regarding all current and former licensees.

(2) The Pharmacy Law provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is

within the Department of Consumer Affairs, and authorizes the board to appoint, with the approval of the Director of Consumer Affairs, an executive officer, as specified. That law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017. Under existing law, the board is subject to evaluation by the Joint Sunset Review Committee upon its repeal.

This bill would extend the operation of the board and the board's authorization to appoint an executive officer until January 1, 2021.

The Pharmacy Law requires each application to conduct a pharmacy, wholesaler, 3rd-party logistics provider, or veterinary food-animal drug retailer to be made on a form furnished by the board and to state specified information. That law requires the executive officer to issue a license to conduct a pharmacy, wholesaler, 3rd-party logistics provider, or veterinary food-animal drug retailer, if specified conditions are met. That law authorizes the board to cancel a license if the licensed premises remains closed, as defined, other than by order of the board. That law requires a licensee whose license is canceled or who notifies the board of its intent to remain closed or to discontinue business to arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee within 10 days. That law authorizes the board to seek and obtain a specified court order authorizing the board to enter the premises, and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the premises if the licensee does not comply with the requirement to do so.

This bill would require an outsourcing facility, as defined, to be licensed with the board before doing business within or into the state. The bill would require each application to conduct an outsourcing facility to be made on a form furnished by the board and to state specified information. The bill would require the executive officer to issue a license if specified conditions are met. The bill would prohibit an outsourcing facility from being concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration (FDA) within 10 days of the action. The bill would prohibit the issuance or renewal of an outsourcing facility license until the board inspects the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to $5,000 per occurrence. The bill would immediately cancel, revoke, or suspend by operation of law the license of any nonresident outsourcing facility whose registration is canceled, revoked, or suspended by the FDA. The bill would authorize the board to cancel an outsourcing facility license if the outsourcing facility remains closed, as defined, other than by order of the board. The bill would require an outsourcing facility licensee whose license is canceled or who notifies the board of its intent to remain closed or to discontinue business to arrange for the transfer of all dangerous drugs

and controlled substances or dangerous devices to another licensee within 10 days. The bill would authorize the board to seek and obtain a specified court order authorizing the board to enter the 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 outsourcing facility if the licensee does not comply with the requirement to do so. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing facilities.

The Pharmacy Law requires a facility licensed by the board to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and requires a facility to update its email address within 30 days of a change in the facility's email address.

This bill would require each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative of a 3rd-party logistics provider licensed in this state to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and to update the licensee's email address within 30 days of a change in the licensee's email address. The bill would prohibit the board from posting those email addresses on the board's license verification system. The bill would make these provisions operative on July 1, 2017.

The Pharmacy Law requires the board to take action against any licensee who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or by mistake and includes, among others, gross immorality as unprofessional conduct. That law also includes 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 under the Pharmacy Law as grounds for unprofessional conduct.

This bill would delete gross immorality as unprofessional conduct and instead provide that procurement of a license by fraud or misrepresentation is unprofessional conduct. This bill would require that revocation, suspension, or other discipline by another state as the basis for similar action under the Pharmacy Law be grounds for revocation, suspension, or other discipline under the Pharmacy Law and requires the board to take action coterminously with action taken by another state. The bill would authorize the board to exceed the term of discipline of another state consistent with the board's enforcement guidelines and provide that evidence of discipline by another state is conclusive proof of unprofessional conduct. The bill would also require the board, to ensure that its resources are maximized for the protection of the public health and safety, to prioritize its investigative and prosecutorial resources to ensure that pharmacists representing the greatest threat of patient harm are identified and disciplined expeditiously.

The Pharmacy Law defines "person" as including a firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision. That law authorizes the board to deny or revoke any license of a corporation, as specified. That law prohibits a person

who has, among other things, been denied a license or whose license has been revoked from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee, as specified, and requires the board to notify in writing each licensee for whom a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the prohibition.

This bill would also define "person" to include, but not be limited to, a trust and would make conforming changes.

The Pharmacy Law requires that fees collected on behalf of the board be credited to the Pharmacy Board Contingent Fund. Existing law continuously appropriates fees in the fund.

This bill would authorize the board to collect a fee of $2,270 for the issuance of an outsourcing facility license, which may be increased to up to $3,180 by the board, a fee of $1,325 for the renewal of that license, which may be increased to up to $1,855 by the board, and a fee of $715 for a temporary outsourcing facility license, as specified. The bill would authorize the board to collect a fee of $2,380 for the issuance of a nonresident outsourcing facility license, which may be increased to up to $3,335 by the board, and a fee of $2,270 for the renewal of that license, which may be increased to up to $3,180 by the board, as specified. The bill would provide that the Pharmacy Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

The Pharmacy Law requires all records of manufacture, and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices to be at all times, during business hours, open to inspection by authorized officers of the law, and to be preserved for at least 3 years from the date of making. That law requires specified entities and individuals to keep a current inventory of these records.

This bill would require an outsourcing facility to keep a current inventory of these records.

The Pharmacy Law authorizes the board to issue a temporary permit to own or operate a pharmacy when the ownership of a pharmacy is transferred from one person to another, as specified.

This bill would authorize the board to issue a temporary permit, as specified, regardless of whether the ownership of a pharmacy is transferred from one person to another.

The Pharmacy Law authorizes a pharmacy to provide pharmacy services to specified licensed health facilities through the use of an automated drug delivery system.

This bill would require a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system to register the system by providing the board in writing with the location of each automated drug delivery system within 30 days of installation and on an annual basis as part of the license renewal. The bill would also require the pharmacy to advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system. The bill would exempt from these requirements an automated drug delivery system operated by a licensed

hospital pharmacy for doses administered in a facility operated under a consolidated license. The bill would authorize a pharmacy to use an automated drug delivery system only if certain conditions are satisfied, including, among other conditions, that the pharmacy report to the board drug losses from the system. The bill would authorize the board to prohibit a pharmacy from using an automated drug delivery system if the board determines that those conditions are not satisfied. The bill would require the board to provide the pharmacy with written notice, as specified, if the board determines those conditions are not satisfied. The bill would authorize the pharmacy, within 30 days of receipt of the written notice, to request an office conference to appeal the board's decision. The bill would authorize the executive officer or designee to affirm or overturn the prohibition as a result of the office conference.

The Pharmacy Law, until January 1, 2012, permitted access by licensed personnel to multiple drugs that are not patient specific only if an automated drug delivery system had both electronic and mechanical safeguards in place to ensure that the only drugs delivered to the patient were specific to that patient. Existing law, until January 1, 2012, required each facility using an automated drug delivery system to notify the State Department of Health Care Services in writing prior to utilization of the system, as provided. Existing law, until January 1, 2012, required the department, as part of its oversight of those facilities, to review a facility's medication training, storage, and security and its administration procedures related to its use of an automated drug delivery system. Existing law authorizes the stocking of an automated drug delivery system to be done outside the facility if the automated drug delivery system utilizes removable pockets, cards, drawers, or similar technology and if certain conditions are met, including that the removable pockets, cards, or drawers are transported in a secured tamper-evident container.

This bill would make these provisions operative by repealing the provision that made them inoperative on January 1, 2012. The bill would additionally authorize the stocking of an automated drug delivery system to be done outside the facility if the system utilizes unit of use or single dose containers, as specified.

The Pharmacy Law requires the board to issue a license, after an investigation to determine whether the applicant and the premises qualify for a license, that authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic.

This bill would require the board, when a clinic applicant submits specified types of applications, to issue a license or incorporate changes to an existing license within 30 days of receipt of a completed application and payment of fees. The bill would require that this provision not be construed to limit the board's authority to investigate to determine whether the applicant and the premises qualify for a license.

The Pharmacy Law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy

license from the board and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding. That law prohibits the board from issuing more than one site license to a single premises with specified exceptions, including issuing a license to compound sterile injectable drugs to a resident pharmacy.

This bill would expand the exception under which the board may issue more than one site license to a single premises to include issuing a license to compound sterile drugs to a pharmacy, regardless of whether those drugs are injectable and regardless of whether the pharmacy is a nonresident pharmacy.

The Pharmacy Law requires a pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation to possess a sterile compounding pharmacy license.

This bill would require a pharmacy that compounds any sterile drug products to possess a sterile compounding pharmacy license.

The Pharmacy Law authorizes the executive officer of the board, based on a reasonable belief obtained during an investigation or pharmacy inspection by the board, to issue a cease and desist order to a pharmacy requiring the pharmacy to refrain from compounding injectable sterile drug products if that activity poses an immediate threat to the public health or safety.

This bill would expand the authorization of the executive officer of the board to issue a cease and desist order to include requiring the pharmacy to refrain from compounding any sterile drug products if that activity poses an immediate threat to public health or safety.

The Pharmacy Law requires a pharmacy to compound injectable sterile products from one or more nonsterile ingredients in a specified environment.

This bill would require a pharmacy to compound any sterile products from one or more nonsterile ingredients in a specified environment.

The Pharmacy Law authorizes the board to issue a temporary license to compound injectable sterile drug products when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, as specified.

This bill would authorize the board to issue a temporary permit to compound sterile drug products, as specified, regardless of whether the drug product is injectable and regardless of whether the ownership of the pharmacy is transferred from one person to another.

The Pharmacy Law requires a resident or a nonresident pharmacy that issues a recall notice regarding a sterile compounded drug to contact, as specified, 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 use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state.

This bill would make a technical correction to this provision and would require a pharmacy that issues a recall notice regarding a nonsterile

compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice, if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state. The bill would also require a pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy to report the event to the MedWatch program of the federal Food and Drug Administration within 72 hours.

The Pharmacy Law authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to the clinic's patients. That law requires each clinic location to have a separate license.

This bill would require the board to synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

Existing law authorizes specified healing arts licensees to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

This bill would additionally authorize licensed pharmacists to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

Existing law authorizes, with the approval of the board and the Department of Justice, a pharmacy or hospital to receive electronic data transmission prescriptions and computer entry prescriptions or orders for controlled substances in Schedule II, III, IV, or V, if authorized by federal law and in accordance with regulations promulgated by the federal Drug Enforcement Administration. Existing law requires the board to maintain a list of all requests and approvals granted. Existing law prohibits an approved pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance in Schedule II, III, IV, or V from being required to reduce that prescription or order to writing or to hard copy form as long as the pharmacy or hospital is able to immediately produce a specified hard copy upon request.

This bill would remove these provisions.

The Pharmacy Law makes a violation of any of its provisions punishable as a misdemeanor or an infraction, as specified.

By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.

(3) The Veterinary Medicine Practice Act provides for the licensure and registration of veterinarians and registered veterinary technicians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board, which is within the Department of Consumer Affairs, and authorizes the board to appoint an executive officer, as specified.

Existing law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017.

This bill would extend the operation of the board and the authorization of the board to appoint an executive officer until January 1, 2021. The bill would authorize a veterinarian or registered veterinary technician who is under the direct supervision of a licensed veterinarian to compound a drug for animal use pursuant to federal law and regulations promulgated by the board and would require those regulations to, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician, and the equipment necessary for safe compounding of drugs.

The Veterinary Medicine Practice Act exempts certain persons from the requirements of the act, including a veterinarian employed by the University of California or the Western University of Health Sciences while engaged in the performance of specified duties. That act requires all premises where veterinary medicine, dentistry, and surgery is being practiced to register with the board. The Veterinary Medicine Practice Act makes a violation of any of its provisions punishable as a misdemeanor.

This bill would instead require a veterinarian engaged in the practice of veterinary medicine employed by the University of California or by the Western University of Health Sciences and engaged in the performance of specified duties to be licensed as a veterinarian in the state or be issued a university license, as specified. The bill would authorize an individual to apply for and be issued a university license if he or she meets certain requirements, including paying an application and license fee. The bill would require a university license, among other things, to automatically cease to be valid upon termination or cessation of employment by the University of California or the Western University of Health Sciences. The bill would also prohibit a premise registration that is not renewed within 5 years after its expiration from being renewed, restored, reissued, or reinstated; however, the bill would authorize a new premise registration to be issued to an applicant if no fact, circumstance, or condition exists that would justify the revocation or suspension of the registration if the registration was issued and if specified fees are paid. By requiring additional persons to be licensed under the act that were previously exempt, the bill would expand the definition of an existing crime and, therefore, would result in a state-mandated local program.

The Veterinary Medicine Practice Act requires all fees collected on behalf of the board to be deposited into the Veterinary Medical Board Contingent Fund, which continuously appropriates fees deposited into the fund.

This bill would provide that the Veterinary Medical Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

(4) This bill would incorporate additional changes in Section 4400 of the Business and Professions Code proposed by SB 1039 that would become operative only if SB 1039 and this bill are both chaptered and become effective on or before January 1, 2017, and this bill is chaptered last.

(5) This bill would incorporate additional changes in Section 4830 of the Business and Professions Code proposed by SB 1039 that would become

operative only if SB 1039 and this bill are both chaptered and become effective on or before January 1, 2017, and this bill is chaptered last.

(6) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 2909.5 of the Business and Professions Code is amended to read:

2909.5. This chapter shall not be construed as restricting or preventing activities of a psychological nature or the use of the official title of the position for which persons were employed on the part of persons who meet the educational requirements of subdivision (b) of Section 2914 and who have one year or more of the supervised professional experience referenced in subdivision (c) of Section 2914, if they are employed by nonprofit community agencies that receive a minimum of 25 percent of their financial support from any federal, state, county, or municipal governmental organizations for the purpose of training and providing services, provided those persons are performing those activities as part of the duties for which they were employed, are performing those activities solely within the confines of or under the jurisdiction of the organization in which they are employed and do not render or offer to render psychological services to the public, as defined in Section 2903. Those persons shall be registered by the agency with the board at the time of employment and shall be identified in the setting as a "registered psychologist." Those persons shall be exempt from this chapter for a maximum period of 30 months from the date of registration.

SEC. 2. Section 2913 of the Business and Professions Code is amended to read:

2913. A person other than a licensed psychologist may perform psychological functions in preparation for licensure as a psychologist only if all of the following conditions are met:

(a) The person shall register himself or herself with the board as a "psychological assistant." This registration shall be renewed annually in accordance with regulations adopted by the board.

(b) The person (1) has completed a master's degree in psychology or education with the field of specialization in psychology or counseling psychology, or (2) has been admitted to candidacy for a doctoral degree in psychology or education with the field of specialization in psychology or counseling psychology, after having satisfactorily completed three or more years of postgraduate education in psychology and having passed preliminary doctoral examinations, or (3) has completed a doctoral degree that qualifies for licensure under Section 2914.

(c) (1) The psychological assistant is at all times under the immediate supervision, as defined in regulations adopted by the board, of a licensed psychologist, or a licensed physician and surgeon who is certified in psychiatry by the American Board of Psychiatry and Neurology or the American College of Osteopathic Board of Neurology and Psychiatry, who shall be responsible for insuring that the extent, kind, and quality of the psychological services that the psychological assistant performs are consistent with his or her training and experience and be responsible for the psychological assistant's compliance with this chapter and regulations.

(2) A licensed psychologist or board certified psychiatrist shall not supervise more than three psychological assistants at any given time. No psychological assistant may provide psychological services to the public except as a supervisee pursuant to this section.

(d) The psychological assistant shall comply with regulations that the board may, from time to time, duly adopt relating to the fulfillment of requirements in continuing education.

SEC. 3. Section 2914 of the Business and Professions Code is amended to read:

2914. Each applicant for licensure shall comply with all of the following requirements:

(a) Is not subject to denial of licensure under Division 1.5 (commencing with Section 475).

(b) Possess an earned doctorate degree (1) in psychology, (2) in educational psychology, or (3) in education with the field of specialization in counseling psychology or educational psychology. Except as provided in subdivision (h), this degree or training shall be obtained from an accredited university, college, or professional school. The board shall make the final determination as to whether a degree meets the requirements of this section.

(c) (1) On or after January 1, 2020, possess an earned doctorate degree in psychology, in educational psychology, or in education with the field of specialization in counseling psychology or educational psychology from a college or institution of higher education that is accredited by a regional accrediting agency recognized by the United States Department of Education. Until January 1, 2020, the board may accept an applicant who possesses a doctorate degree in psychology, educational psychology, or in education with the field of specialization in counseling psychology or educational psychology from an institution that is not accredited by an accrediting agency recognized by the United States Department of Education, but is approved to operate in this state by the Bureau for Private Postsecondary Education.

(2) Paragraph (1) does not apply to any student who was enrolled in a doctoral program in psychology, educational psychology, or in education with the field of specialization in counseling psychology or educational psychology at a nationally accredited or approved institution as of December 31, 2016.

(3) No educational institution shall be denied recognition as an accredited academic institution solely because its program is not accredited by any professional organization of psychologists, and nothing in this chapter or

in the administration of this chapter shall require the registration with the board by educational institutions of their departments of psychology or their doctoral programs in psychology.

(4) An applicant for licensure trained in an educational institution outside the United States or Canada shall demonstrate to the satisfaction of the board that he or she possesses a doctorate degree in psychology that is equivalent to a degree earned from a regionally accredited university in the United States or Canada. These applicants shall provide the board with a comprehensive evaluation of the degree performed by a foreign credential evaluation service that is a member of the National Association of Credential Evaluation Services (NACES), and any other documentation the board deems necessary.

(d) (1) Have engaged for at least two years in supervised professional experience under the direction of a licensed psychologist, the specific requirements of which shall be defined by the board in its regulations, or under suitable alternative supervision as determined by the board in regulations duly adopted under this chapter, at least one year of which shall be after being awarded the doctorate in psychology. The supervisor shall submit verification of the experience required by this subdivision to the trainee in a manner prescribed by the board. If the supervising licensed psychologist fails to provide verification to the trainee in a timely manner, the board may establish alternative procedures for obtaining the necessary documentation. Absent good cause, the failure of a supervising licensed psychologist to provide the verification to the board upon request shall constitute unprofessional conduct.

(2) The board shall establish qualifications by regulation for supervising psychologists.

(e) Take and pass the examination required by Section 2941 unless otherwise exempted by the board under this chapter.

(f) Show by evidence satisfactory to the board that he or she has completed training in the detection and treatment of alcohol and other chemical substance dependency. This requirement applies only to applicants who matriculate on or after September 1, 1985.

(g) (1) Show by evidence satisfactory to the board that he or she has completed coursework in spousal or partner abuse assessment, detection, and intervention. This requirement applies to applicants who began graduate training during the period commencing on January 1, 1995, and ending on December 31, 2003.

(2) An applicant who began graduate training on or after January 1, 2004, shall show by evidence satisfactory to the board that he or she has completed a minimum of 15 contact hours of coursework in spousal or partner abuse assessment, detection, and intervention strategies, including knowledge of community resources, cultural factors, and same gender abuse dynamics. An applicant may request an exemption from this requirement if he or she intends to practice in an area that does not include the direct provision of mental health services.

(3) Coursework required under this subdivision may be satisfactory if taken either in fulfillment of other educational requirements for licensure or in a separate course. This requirement for coursework shall be satisfied by, and the board shall accept in satisfaction of the requirement, a certification from the chief academic officer of the educational institution from which the applicant graduated that the required coursework is included within the institution's required curriculum for graduation.

(h) Until January 1, 2020, an applicant holding a doctoral degree in psychology from an approved institution is deemed to meet the requirements of this section if both of the following are true:

(1) The approved institution offered a doctoral degree in psychology designed to prepare students for a license to practice psychology and was approved by the former Bureau for Private Postsecondary and Vocational Education on or before July 1, 1999.

(2) The approved institution has not, since July 1, 1999, had a new location, as described in Section 94823.5 of the Education Code.

SEC. 4. Section 2914.1 of the Business and Professions Code is amended to read:

2914.1. The board shall encourage every licensed psychologist to take continuing professional development in geriatric pharmacology.

SEC. 5. Section 2914.2 of the Business and Professions Code is amended to read:

2914.2. The board shall encourage licensed psychologists to take continuing professional development in psychopharmacology and biological basis of behavior.

SEC. 6. Section 2915 of the Business and Professions Code is amended to read:

2915. (a) Except as provided in this section, the board shall issue a renewal license only to an applicant who has completed 36 hours of approved continuing professional development in the preceding two years.

(b) Each person who applies to renew or reinstate his or her license issued pursuant to this chapter shall certify under penalty of perjury that he or she is in compliance with this section and shall retain proof of this compliance for submission to the board upon request. False statements submitted pursuant to this section shall be a violation of Section 2970.

(c) Continuing professional development means certain continuing education learning activities approved in four different categories:

(1) Professional.

(2) Academic.

(3) Sponsored continuing education coursework.

(4) Board certification from the American Board of Professional Psychology.

The board may develop regulations further defining acceptable continuing professional development activities.

(d) (1) The board shall require a licensed psychologist who began graduate study prior to January 1, 2004, to take a continuing education course during his or her first renewal period after the operative date of this

section in spousal or partner abuse assessment, detection, and intervention strategies, including community resources, cultural factors, and same gender abuse dynamics. Equivalent courses in spousal or partner abuse assessment, detection, and intervention strategies taken prior to the operative date of this section or proof of equivalent teaching or practice experience may be submitted to the board and at its discretion, may be accepted in satisfaction of this requirement.

(2) Continuing education courses taken pursuant to this subdivision shall be applied to the 36 hours of approved continuing professional development required under subdivision (a).

(e) Continuing education courses approved to meet the requirements of this section shall be approved by organizations approved by the board. An organization previously approved by the board to provide or approve continuing education is deemed approved under this section.

(f) The board may accept continuing education courses approved by an entity that has demonstrated to the board in writing that it has, at a minimum, a 10-year history of providing educational programming for psychologists and has documented procedures for maintaining a continuing education approval program. The board shall adopt regulations necessary for implementing this section.

(g) The board may grant an exemption, or an extension of the time for compliance with, from the continuing professional development requirement of this section.

(h) The administration of this section may be funded through professional license fees and continuing education provider and course approval fees, or both. The fees related to the administration of this section shall not exceed the costs of administering the corresponding provisions of this section.

SEC. 7. Section 2920 of the Business and Professions Code is amended to read:

2920. (a) The Board of Psychology shall enforce and administer this chapter. The board shall consist of nine members, four of whom shall be public members.

(b) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 8. Section 2933 of the Business and Professions Code is amended to read:

2933. (a) Except as provided by Section 159.5, the board shall employ and shall make available to the board within the limits of the funds received by the board all personnel necessary to carry out this chapter. The board may employ, exempt from the State Civil Service Act, an executive officer to the Board of Psychology. The board shall make all expenditures to carry out this chapter. The board may accept contributions to effectuate the purposes of this chapter.

(b) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 9. Section 2934.1 is added to the Business and Professions Code, to read:

2934.1. (a) The board may post on its Internet Web site the following information on the current status of the license for all current and former licensees:

(1) Whether or not the licensee has a record of a disciplinary action.

(2) Any of the following enforcement actions or proceedings against the licensee:

(A) Temporary restraining orders.

(B) Interim suspension orders.

(C) Revocations, suspensions, probations, or limitations on practice ordered by the board or by a court with jurisdiction in the state, including those made part of a probationary order, cease practice order, or stipulated agreement.

(D) Accusations filed by the board, including those accusations that are on appeal, excluding ones that have been dismissed or withdrawn where the action is no longer pending.

(E) Citations issued by the board. Unless withdrawn, citations shall be posted for five years from the date of issuance.

(b) The board may also post on its Internet Web site all of the following historical information in its possession, custody, or control regarding all current and former licensees:

(1) Institutions that awarded the qualifying educational degree and type of degree awarded.

(2) A link to the licensee's professional Internet Web site. Any link that provides access to a licensee's professional Internet Web site, once clicked, shall be accompanied by a notification that informs the Internet Web site viewer that they are no longer on the board's Internet Web site.

(c) The board may also post other information designated by the board in regulation.

SEC. 10. Section 2947 of the Business and Professions Code is repealed.

SEC. 11. Section 2988.5 is added to the Business and Professions Code, to read:

2988.5. (a) The board may issue, upon an application prescribed by the board and payment of a fee not to exceed seventy-five dollars ($75), a retired license to a psychologist who holds a current license issued by the board, or one capable of being renewed, and whose license is not suspended, revoked, or otherwise restricted by the board or subject to discipline under this chapter.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active license is required. A psychologist holding a retired license shall be permitted to use the title "psychologist, retired" or "retired psychologist." The designation of retired shall not be abbreviated in any way.

(c) A retired license shall not be subject to renewal.

(d) The holder of a retired license may apply to obtain an active status license as follows:

(1) If that retired license was issued less than three years prior to the application date, the applicant shall meet all of the following requirements:

(A) Has not committed an act or crime constituting grounds for denial or discipline of a license.

(B) Pays the renewal fee required by this chapter.

(C) Completes the continuing professional development required for the renewal of a license within two years of the date of application for restoration.

(D) Complies with the fingerprint submission requirements established by the board.

(2) Where the applicant has held a retired license for three or more years, the applicant shall do all of the following:

(A) Submit a complete application for a new license.

(B) Take and pass the California Psychology Law and Ethics Examination.

(C) Pay all fees required to obtain a new license.

(D) Comply with the fingerprint submission requirements established by the board.

(E) Be deemed to have met the educational and experience requirements of subdivisions (b) and (c) of Section 2914.

(F) Establish that he or she has not been subject to denial or discipline of a license.

SEC. 12. Section 4001 of the Business and Professions Code is amended to read:

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

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a “chain community pharmacy” means a chain of 75 or more stores in California under the same ownership, and an “independent community pharmacy” means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) 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.

SEC. 13. Section 4003 of the Business and Professions Code is amended to read:

4003. (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.

SEC. 14. Section 4013 of the Business and Professions Code is amended to read:

4013. (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.

SEC. 15. Section 4034 is added to the Business and Professions Code, to read:

4034. "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).

SEC. 16. Section 4035 of the Business and Professions Code is amended to read:

4035. "Person" includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision.

SEC. 17. Section 4081 of the Business and Professions Code is amended to read:

4081. (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.

SEC. 18. Section 4105.5 is added to the Business and Professions Code, to read:

4105.5. (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).

SEC. 19. Section 4107 of the Business and Professions Code is amended to read:

4107. (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.

SEC. 20. Section 4110 of the Business and Professions Code is amended to read:

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit 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.

SEC. 21. Section 4119.1 of the Business and Professions Code is amended to read:

4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

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

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

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) 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.

SEC. 22. Section 4126.9 is added to the Business and Professions Code, to read:

4126.9. (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.

SEC. 23. Section 4127 of the Business and Professions Code is amended to read:

4127. (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).

SEC. 24. Section 4127.3 of the Business and Professions Code is amended to read:

4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding 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.

SEC. 25. Section 4127.7 of the Business and Professions Code is amended to read:

4127.7. 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.

SEC. 26. Section 4127.8 of the Business and Professions Code is amended to read:

4127.8. 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.

SEC. 27. Section 4127.9 of the Business and Professions Code is amended to read:

4127.9. (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.

SEC. 28. Section 4128.6 of the Business and Professions Code is amended to read:

4128.6. 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.

SEC. 29. Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.7. Outsourcing Facilities

4129. (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. (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. (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. (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. (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. 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. 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. (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.

SEC. 30. Section 4161 of the Business and Professions Code is amended to read:

4161. (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.

SEC. 31. Section 4180 of the Business and Professions Code is amended to read:

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (*l*) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

(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.

SEC. 32. Section 4201 of the Business and Professions Code is amended to read:

4201. (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.

SEC. 33. Section 4203.5 is added to the Business and Professions Code, to read:

4203.5. (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.

SEC. 34. Section 4301 of the Business and Professions Code is amended to read:

4301. 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.

SEC. 35. Section 4301.1 is added to the Business and Professions Code, to read:

4301.1. 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.

SEC. 36. Section 4302 of the Business and Professions Code is amended to read:

4302. 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.

SEC. 37. Section 4303.1 is added to the Business and Professions Code, to read:

4303.1. 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.

SEC. 38. Section 4307 of the Business and Professions Code is amended to read:

4307. (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, 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.

SEC. 39. Section 4308 of the Business and Professions Code is amended to read:

4308. Whenever a person is 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 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.

SEC. 40. Section 4312 of the Business and Professions Code is amended to read:

4312. (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.

SEC. 41. Section 4316 is added to the Business and Professions Code, to read:

4316. (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.

SEC. 42. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be 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) 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.

SEC. 42.5. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be 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) 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) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

SEC. 43. Section 4406 of the Business and Professions Code is amended to read:

4406. All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the 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.

SEC. 44. Section 4800 of the Business and Professions Code is amended to read:

4800. (a) There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of the following members:

(1) Four licensed veterinarians.

(2) One registered veterinary technician.

(3) Three public members.

(b) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to those issues identified by the appropriate policy committees of the Legislature and shall not involve the preparation or submission of a sunset review document or evaluative questionnaire.

SEC. 45. Section 4804.5 of the Business and Professions Code is amended to read:

4804.5. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 46. Section 4826.5 is added to the Business and Professions Code, to read:

4826.5. Notwithstanding any other law, a licensed veterinarian or a registered veterinary technician under the supervision of a licensed veterinarian may compound drugs for animal use pursuant to Section 530 of Title 21 of the Code of Federal Regulations and in accordance with regulations promulgated by the board. The regulations promulgated by the board shall, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician, and the equipment necessary for the safe compounding of drugs. Any violation of the regulations adopted by the board pursuant to this section shall constitute grounds for an enforcement or disciplinary action.

SEC. 47. Section 4830 of the Business and Professions Code is amended to read:

4830. (a) This chapter does not apply to:

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.

(2) Regularly licensed veterinarians in actual consultation from other states.

(3) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.

(4) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

(5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

(6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or

administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

(A) The temporary shelter facility is established only for the purpose of the investigation.

(B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.

(C) The temporary shelter facility complies with Section 4854.

(D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.

(E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.

(c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.

SEC. 47.5. Section 4830 of the Business and Professions Code is amended to read:

4830. (a) This chapter does not apply to:

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.

(2) Veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case. The California licensed veterinarian shall maintain a valid veterinarian-client-patient relationship. The veterinarian providing the assistance shall not establish a veterinarian-client-patient relationship with the client by attending the case or at a future time and shall not practice veterinary medicine, open an office, appoint a place to meet patients, communicate with clients who reside within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient that is located within this state.

(3) Veterinarians called into the state by a law enforcement agency or animal control agency pursuant to subdivision (b).

(4) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

(5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

(6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to

attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

(A) The temporary shelter facility is established only for the purpose of the investigation.

(B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.

(C) The temporary shelter facility complies with Section 4854.

(D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.

(E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.

(c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.

SEC. 48. Section 4846.5 of the Business and Professions Code is amended to read:

4846.5. (a) Except as provided in this section, the board shall issue renewal licenses only to those applicants that have completed a minimum of 36 hours of continuing education in the preceding two years.

(b) (1) Notwithstanding any other law, continuing education hours shall be earned by attending courses relevant to veterinary medicine and sponsored or cosponsored by any of the following:

(A) American Veterinary Medical Association (AVMA) accredited veterinary medical colleges.

(B) Accredited colleges or universities offering programs relevant to veterinary medicine.

(C) The American Veterinary Medical Association.

(D) American Veterinary Medical Association recognized specialty or affiliated allied groups.

(E) American Veterinary Medical Association's affiliated state veterinary medical associations.

(F) Nonprofit annual conferences established in conjunction with state veterinary medical associations.

(G) Educational organizations affiliated with the American Veterinary Medical Association or its state affiliated veterinary medical associations.

(H) Local veterinary medical associations affiliated with the California Veterinary Medical Association.

(I) Federal, state, or local government agencies.

(J) Providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) or approved by the American Medical Association (AMA), providers recognized by the American Dental Association Continuing Education Recognition Program (ADA CERP), and AMA or ADA affiliated state, local, and specialty organizations.

(2) Continuing education credits shall be granted to those veterinarians taking self-study courses, which may include, but are not limited to, reading journals, viewing video recordings, or listening to audio recordings. The taking of these courses shall be limited to no more than six hours biennially.

(3) The board may approve other continuing veterinary medical education providers not specified in paragraph (1).

(A) The board has the authority to recognize national continuing education approval bodies for the purpose of approving continuing education providers not specified in paragraph (1).

(B) Applicants seeking continuing education provider approval shall have the option of applying to the board or to a board-recognized national approval body.

(4) For good cause, the board may adopt an order specifying, on a prospective basis, that a provider of continuing veterinary medical education authorized pursuant to paragraph (1) or (3) is no longer an acceptable provider.

(5) Continuing education hours earned by attending courses sponsored or cosponsored by those entities listed in paragraph (1) between January 1, 2000, and January 1, 2001, shall be credited toward a veterinarian's continuing education requirement under this section.

(c) Every person renewing his or her license issued pursuant to Section 4846.4, or any person applying for relicensure or for reinstatement of his or her license to active status, shall submit proof of compliance with this section to the board certifying that he or she is in compliance with this section. Any false statement submitted pursuant to this section shall be a violation subject to Section 4831.

(d) This section shall not apply to a veterinarian's first license renewal. This section shall apply only to second and subsequent license renewals granted on or after January 1, 2002.

(e) The board shall have the right to audit the records of all applicants to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a period of four years and shall make these records available to the board for auditing purposes upon request. If the board, during this audit, questions whether any course reported by the veterinarian satisfies the continuing education requirement, the veterinarian shall provide information to the board concerning the content of the course; the name of its sponsor and cosponsor, if any; and specify the specific curricula that was of benefit to the veterinarian.

(f) A veterinarian desiring an inactive license or to restore an inactive license under Section 701 shall submit an application on a form provided by the board. In order to restore an inactive license to active status, the

veterinarian shall have completed a minimum of 36 hours of continuing education within the last two years preceding application. The inactive license status of a veterinarian shall not deprive the board of its authority to institute or continue a disciplinary action against a licensee.

(g) Knowing misrepresentation of compliance with this article by a veterinarian constitutes unprofessional conduct and grounds for disciplinary action or for the issuance of a citation and the imposition of a civil penalty pursuant to Section 4883.

(h) The board, in its discretion, may exempt from the continuing education requirement any veterinarian who for reasons of health, military service, or undue hardship cannot meet those requirements. Applications for waivers shall be submitted on a form provided by the board.

(i) The administration of this section may be funded through professional license and continuing education provider fees. The fees related to the administration of this section shall not exceed the costs of administering the corresponding provisions of this section.

(j) For those continuing education providers not listed in paragraph (1) of subdivision (b), the board or its recognized national approval agent shall establish criteria by which a provider of continuing education shall be approved. The board shall initially review and approve these criteria and may review the criteria as needed. The board or its recognized agent shall monitor, maintain, and manage related records and data. The board may impose an application fee, not to exceed two hundred dollars ($200) biennially, for continuing education providers not listed in paragraph (1) of subdivision (b).

(k) (1) Beginning January 1, 2018, a licensed veterinarian who renews his or her license shall complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs every four years as part of his or her continuing education requirements.

(2) For purposes of this subdivision, “medically important antimicrobial drug” means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration’s Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

SEC. 49. Section 4848.1 is added to the Business and Professions Code, to read:

4848.1. (a) A veterinarian engaged in the practice of veterinary medicine, as defined in Section 4826, employed by the University of California and engaged in the performance of duties in connection with the School of Veterinary Medicine or employed by the Western University of Health Sciences and engaged in the performance of duties in connection with the College of Veterinary Medicine shall be issued a university license pursuant to this section or hold a license to practice veterinary medicine in this state.

(b) An individual may apply for and be issued a university license if all of the following are satisfied:

(1) He or she is currently employed by the University of California or Western University of Health Sciences, as defined in subdivision (a).

(2) He or she passes an examination concerning the statutes and regulations of the Veterinary Medicine Practice Act, administered by the board, pursuant to subparagraph (C) of paragraph (2) of subdivision (a) of Section 4848.

(3) He or she successfully completes the approved educational curriculum described in paragraph (5) of subdivision (b) of Section 4848 on regionally specific and important diseases and conditions.

(4) He or she completes and submits the application specified by the board and pays the application fee, pursuant to subdivision (g) of Section 4905, and the initial license fee, pursuant to subdivision (h) of Section 4905.

(c) A university license:

(1) Shall be numbered as described in Section 4847.

(2) Shall automatically cease to be valid upon termination or cessation of employment by the University of California or by the Western University of Health Sciences.

(3) Shall be subject to the license renewal provisions in Section 4846.4 and the payment of the renewal fee pursuant to subdivision (i) of Section 4905.

(4) Shall be subject to denial, revocation, or suspension pursuant to Sections 480, 4875, and 4883.

(5) Authorizes the holder to practice veterinary medicine only at an educational institution described in subdivision (a) and any locations formally affiliated with those institutions.

(d) An individual who holds a university license is exempt from satisfying the license renewal requirements of Section 4846.5.

SEC. 50. Section 4853.7 is added to the Business and Professions Code, to read:

4853.7. A premise registration that is not renewed within five years after its expiration may not be renewed and shall not be restored, reissued, or reinstated thereafter. However, an application for a new premise registration may be submitted and obtained if both of the following conditions are met:

(a) No fact, circumstance, or condition exists that, if the premise registration was issued, would justify its revocation or suspension.

(b) All of the fees that would be required for the initial premise registration are paid at the time of application.

SEC. 51. Section 4904 of the Business and Professions Code is amended to read:

4904. 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 Veterinary Medical Board Contingent Fund. This contingent fund shall be available, upon appropriation by the Legislature, for the use of the Veterinary Medical Board.

SEC. 52. Section 4905 of the Business and Professions Code is amended to read:

4905. The following fees shall be collected by the board and shall be credited to the Veterinary Medical Board Contingent Fund:

(a) The fee for filing an application for examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars ($350).

(b) The fee for the California state board examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars ($350).

(c) The fee for the Veterinary Medicine Practice Act examination shall be set by the board in an amount it determines reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed one hundred dollars ($100).

(d) The initial license fee shall be set by the board not to exceed five hundred dollars ($500) except that, if the license is issued less than one year before the date on which it will expire, then the fee shall be set by the board not to exceed two hundred fifty dollars ($250). The board may, by appropriate regulation, provide for the waiver or refund of the initial license fee where the license is issued less than 45 days before the date on which it will expire.

(e) The renewal fee shall be set by the board for each biennial renewal period in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed five hundred dollars ($500).

(f) The temporary license fee shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed two hundred fifty dollars ($250).

(g) The fee for filing an application for a university license shall be one hundred twenty-five dollars ($125), which may be revised by the board in regulation but shall not exceed three hundred fifty dollars ($350).

(h) The initial license fee for a university license shall be two hundred ninety dollars ($290), which may be revised by the board in regulation but shall not exceed five hundred dollars ($500).

(i) The biennial renewal fee for a university license shall be two hundred ninety dollars ($290), which may be revised by the board in regulation but shall not exceed five hundred dollars ($500).

(j) The delinquency fee shall be set by the board, not to exceed fifty dollars ($50).

(k) The fee for issuance of a duplicate license is twenty-five dollars ($25).

(*l*) Any charge made for duplication or other services shall be set at the cost of rendering the service, except as specified in subdivision (k).

(m) The fee for failure to report a change in the mailing address is twenty-five dollars ($25).

(n) The initial and annual renewal fees for registration of veterinary premises shall be set by the board in an amount not to exceed four hundred dollars ($400) annually.

(o) If the money transferred from the Veterinary Medical Board Contingent Fund to the General Fund pursuant to the Budget Act of 1991

is redeposited into the Veterinary Medical Board Contingent Fund, the fees assessed by the board shall be reduced correspondingly. However, the reduction shall not be so great as to cause the Veterinary Medical Board Contingent Fund to have a reserve of less than three months of annual authorized board expenditures. The fees set by the board shall not result in a Veterinary Medical Board Contingent Fund reserve of more than 10 months of annual authorized board expenditures.

SEC. 53. Section 13401.5 of the Corporations Code is amended to read:

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation. This section does not limit employment by a professional corporation designated in this section to only those licensed professionals listed under each subdivision. Any person duly licensed under Division 2 (commencing with Section 500) of the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act may be employed to render professional services by a professional corporation designated in this section.

(a) Medical corporation.
(1) Licensed doctors of podiatric medicine.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(12) Licensed physical therapists.
(13) Licensed pharmacists.
(b) Podiatric medical corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed physical therapists.
(c) Psychological corporation.

(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed chiropractors.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(10) Licensed professional clinical counselors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(g) Marriage and family therapist corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed professional clinical counselors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed professional clinical counselors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.

(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(10) Licensed professional clinical counselors.
(*l*) Acupuncture corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.
(9) Licensed marriage and family therapists.
(10) Licensed clinical social workers.
(11) Licensed optometrists.
(12) Licensed professional clinical counselors.
(n) Dental corporation.

(1) Licensed physicians and surgeons.
(2) Dental assistants.
(3) Registered dental assistants.
(4) Registered dental assistants in extended functions.
(5) Registered dental hygienists.
(6) Registered dental hygienists in extended functions.
(7) Registered dental hygienists in alternative practice.
(o) Professional clinical counselor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Licensed marriage and family therapists.
(5) Registered nurses.
(6) Licensed chiropractors.
(7) Licensed acupuncturists.
(8) Naturopathic doctors.
(p) Physical therapy corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(5) Licensed occupational therapists.
(6) Licensed speech-language therapists.
(7) Licensed audiologists.
(8) Registered nurses.
(9) Licensed psychologists.
(10) Licensed physician assistants.
(q) Registered dental hygienist in alternative practice corporation.
(1) Registered dental assistants.
(2) Licensed dentists.
(3) Registered dental hygienists.
(4) Registered dental hygienists in extended functions.

SEC. 54. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

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

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

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

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

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

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

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

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

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

SEC. 55. Section 11164.5 of the Health and Safety Code is amended to read:

11164.5. (a) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(b) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

SEC. 56. Section 42.5 of this bill incorporates amendments to Section 4400 of the Business and Professions Code proposed by both this bill and Senate Bill 1039. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2017, (2) each bill amends Section 4400 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1039, in which case Section 42 of this bill shall not become operative.

SEC. 57. Section 47.5 of this bill incorporates amendments to Section 4830 of the Business and Professions Code proposed by both this bill and Senate Bill 1039. It shall only become operative if (1) both bills are enacted

and become effective on or before January 1, 2017, (2) each bill amends Section 4830 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1039, in which case Section 47 of this bill shall not become operative.

SEC. 58. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Senate Bill No. 1039

CHAPTER 799

An act to amend Sections 655, 1944, 2733, 2786.5, 2811, 2811.5, 2815, 2815.5, 2816, 2830.7, 2836.3, 2838.2, 4128.2, 4830, 4999, 4999.2, 8516, and 8518 of, to amend, repeal, and add Sections 4400, 7137, and 7153.3 of, to add Sections 2746.53 and 3030 to, to repeal Sections 4999.1, 4999.3, 4999.4, and 4999.6 of, and to repeal and add Sections 2546.9, 2565, 2566, 2566.1, and 4999.5 of, the Business and Professions Code, to amend Section 1348.8 of the Health and Safety Code, and to amend Section 10279 of the Insurance Code, relating to professions and vocations, and making an appropriation therefor.

[Approved by Governor September 29, 2016. Filed with
Secretary of State September 29, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1039, Hill. Professions and vocations.

(1) Existing law requires the Office of Statewide Health Planning and Development to establish the Health Professions Education Foundation to, among other things, solicit and receive funds for the purpose of providing scholarships, as specified.

The bill would state the intent of the Legislature to enact future legislation that would establish a Dental Corps Scholarship Program, as specified, to increase the supply of dentists serving in medically underserved areas.

(2) Existing law, the Dental Practice Act, requires the Dental Hygiene Committee of California to establish by resolution the amount of the fees that relate to the licensing of a registered dental hygienist, a registered dental hygienist in alternative practice, and a registered dental hygienist in extended functions. Existing law prohibits the biennial renewal fee from exceeding $160. Existing law requires these fees to be deposited in the State Dental Hygiene Fund and makes these moneys subject to appropriation by the Legislature.

This bill would instead prohibit the biennial renewal fee from exceeding $500.

(3) Existing law makes the State Board of Optometry responsible for the regulation of nonresident contact lens sellers, registered dispensing opticians, spectacle lens dispensers, and contact lens dispensers.

Existing law authorizes the State Board of Optometry to issue a citation containing an order of abatement, an order to pay an administrative fine not to exceed $50,000, or both, as specified, for a violation of a specific section of law governing the permitted relationship of an optometrist with any registered dispensing optician or any optical company.

This bill would make that $50,000 limit a limit per investigation.

Existing law establishes regulatory fees for the regulation of nonresident contact lens sellers, registered dispensing opticians, spectacle lens dispensers, and contact lens dispensers, including, but not limited to, an initial registration fee, a renewal fee, and a delinquency fee. Existing law requires these fees to be deposited in the Dispensing Opticians Fund and makes these fees available, subject to appropriation, to the State Board of Optometry.

This bill would establish a specified minimum and maximum application fee amount for nonresident contact lens sellers, registered dispensing opticians, and spectacle lens dispensers. The bill would also establish increased minimum and maximum amounts for those already established fees. The bill would authorize the State Board of Optometry to periodically revise and fix these fees, as specified.

Existing law authorizes the State Board of Optometry to inspect any premises at which the business of a registered dispensing optician is colocated with the practice of an optometrist for the purposes of determining compliance with the aforementioned written lease agreement provisions.

This bill would authorize the State Board of Optometry at any time to inspect the premises registered with the board in which optometry is being practiced or in which spectacle or contact lenses are fitted or dispensed.

(4) The Nursing Practice Act provides for the licensure and regulation of nurse practitioners by the Board of Registered Nursing, which is within the Department of Consumer Affairs, and requires the board to adopt regulations establishing standards for continuing education for licensees, as specified. That act requires providers of continuing education programs approved by the board to make records of continuing education courses given to registered nurses available for board inspection. That act also prescribes various fees to be paid by licensees and applicants for licensure, and requires these fees to be credited to the Board of Registered Nursing Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would require that the content of a continuing education course be based on generally accepted scientific principles. The bill would also require the board to audit continuing education providers, at least once every 5 years, to ensure adherence to regulatory requirements, and to withhold or rescind approval from any provider that is in violation of regulatory requirements. The bill would raise specified fees, and would provide for additional fees, to be paid by licensees and applicants for licensure pursuant to that act. By increasing fees deposited into a continuously appropriated fund, this bill would make an appropriation.

(5) The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy within the Department of Consumer Affairs. That law prescribes various fees to be paid by licensees and applicants for licensure, and requires all fees collected on behalf of the board to be credited to the Pharmacy Board Contingent Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would, on and after July 1, 2017, modify specified fees to be paid by licensees and applicants for licensure pursuant to that act. By increasing fees deposited into a continuously appropriated fund, this bill would make an appropriation.

(6) The Veterinary Medicine Practice Act provides for the licensure and regulation of veterinarians by the Veterinary Medical Board, which is within the Department of Consumer Affairs. Under the act, it is unlawful and a misdemeanor for any person to practice veterinary medicine in this state unless he or she holds a valid, unexpired, and unrevoked license issued by the board, except under specified circumstances, including regularly licensed veterinarians in actual consultation from other states, regularly licensed veterinarians actually called from other states to attend cases in this state who do not open an office or appoint a place to do business within the state, or veterinarians employed by the University of California or the Western University of Health Sciences while engaged in the performance of specified duties.

This bill would replace those exceptions with an exception for veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case, subject to specified conditions, and an exception for veterinarians called into the state by a law enforcement agency or animal control agency. By requiring additional persons to be licensed under the act that were previously exempt, the bill would expand the definition of an existing crime and, therefore, would result in a state-mandated local program.

(7) Existing law requires businesses that employ, or contract or subcontract with, the full-time equivalent of 5 or more persons functioning as health care professionals, as defined, whose primary function is to provide telephone medical advice, that provide telephone medical advice services to a patient at a California address to be registered with the Telephone Medical Advice Services Bureau and further requires telephone medical advice services to comply with the requirements established by the Department of Consumer Affairs, as specified.

This bill would discontinue the requirement that those businesses be registered with the bureau, would instead make the respective healing arts licensing boards responsible for enforcing those requirements and any other laws and regulations affecting those health care professionals licensed in California, and would make conforming and related changes.

(8) The Contractors' State License Law provides for the licensure and regulation of contractors by the Contractors' State License Board within the Department of Consumer Affairs. That law also prescribes various fees to be paid by licensees and applicants for licensure, requires the board to set the fees by regulation, and requires fees and civil penalties received under that law to be deposited in the Contractors' License Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill, on and after July 1, 2017, would raise specified fees, would instead authorize the board to set the fees by regulation, and would require

the board to establish criteria for the approval of expedited processing of applications, as specified. By increasing fees deposited into a continuously appropriated fund, this bill would make an appropriation.

(9) Existing law provides for the licensure and regulation of structural pest control operators and registered companies by the Structural Pest Control Board, which is within the Department of Consumer Affairs, and requires a licensee to pay a specified license fee. Existing law makes any violation of those provisions punishable as a misdemeanor. Existing law places certain requirements on a registered company or licensee with regards to wood destroying pests or organisms, including that a registered company or licensee is prohibited from commencing work on a contract until an inspection has been made by a licensed Branch 3 field representative or operator, that the address of each property inspected or upon which work was completed is required to be reported to the board, as specified, and that a written inspection report be prepared and delivered to the person requesting the inspection or his or her agent. Existing law requires the original inspection report to be submitted to the board upon demand. Existing law requires that written report to contain certain information, including a foundation diagram or sketch of the structure or portions of the structure inspected, and requires the report, and any contract entered into, to expressly state if a guarantee for the work is made, and if so, the terms and time period of the guarantee. Existing law establishes the Structural Pest Control Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would require the operator who is conducting the inspection prior to the commencement of work to be employed by a registered company, except as specified. The bill would not require the address of an inspection report prepared for use by an attorney for litigation to be reported to the board or assessed a filing fee. The bill would require instead that the written inspection report be prepared and delivered to the person requesting it, the property owner, or the property owner's designated agent, as specified. The bill would allow an inspection report to be a complete, limited, supplemental, or reinspection report, as defined. The bill would require all inspection reports to be submitted to the board and maintained with field notes, activity forms, and notices of completion until one year after the guarantee expires if the guarantee extends beyond 3 years. The bill would require the inspection report to clearly list the infested or infected wood members or parts of the structure identified in the required diagram or sketch. By placing new requirements on a registered company or licensee, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.

Existing law requires a registered company to prepare a notice of work completed to give to the owner of the property when the work is completed.

This bill would make this provision applicable only to work relating to wood destroying pests and organisms.

(10) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to enact future legislation that would establish a Dental Corps Scholarship Program within the Health Professions Education Foundation to increase the supply of dentists serving in medically underserved areas.

SEC. 2. Section 655 of the Business and Professions Code is amended to read:

655. (a) For the purposes of this section, the following terms have the following meanings:

(1) "Health plan" means a health care service plan licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(2) "Optical company" means a person or entity that is engaged in the manufacture, sale, or distribution to physicians and surgeons, optometrists, health plans, or dispensing opticians of lenses, frames, optical supplies, or optometric appliances or devices or kindred products.

(3) "Optometrist" means a person licensed pursuant to Chapter 7 (commencing with Section 3000) or an optometric corporation, as described in Section 3160.

(4) "Registered dispensing optician" means a person licensed pursuant to Chapter 5.5 (commencing with Section 2550).

(5) "Therapeutic ophthalmic product" means lenses or other products that provide direct treatment of eye disease or visual rehabilitation for diseased eyes.

(b) No optometrist may have any membership, proprietary interest, coownership, or any profit-sharing arrangement, either by stock ownership, interlocking directors, trusteeship, mortgage, or trust deed, with any registered dispensing optician or any optical company, except as otherwise permitted under this section.

(c) (1) A registered dispensing optician or an optical company may operate, own, or have an ownership interest in a health plan so long as the health plan does not directly employ optometrists to provide optometric services directly to enrollees of the health plan, and may directly or indirectly provide products and services to the health plan or its contracted providers or enrollees or to other optometrists. For purposes of this section, an optometrist may be employed by a health plan as a clinical director for the health plan pursuant to Section 1367.01 of the Health and Safety Code or

to perform services related to utilization management or quality assurance or other similar related services that do not require the optometrist to directly provide health care services to enrollees. In addition, an optometrist serving as a clinical director may not employ optometrists to provide health care services to enrollees of the health plan for which the optometrist is serving as clinical director. For the purposes of this section, the health plan's utilization management and quality assurance programs that are consistent with 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) do not constitute providing health care services to enrollees.

(2) The registered dispensing optician or optical company shall not interfere with the professional judgment of the optometrist.

(3) The Department of Managed Health Care shall forward to the State Board of Optometry any complaints received from consumers that allege that an optometrist violated the Optometry Practice Act (Chapter 7 (commencing with Section 3000)). The Department of Managed Health Care and the State Board of Optometry shall enter into an Inter-Agency Agreement regarding the sharing of information related to the services provided by an optometrist that may be in violation of the Optometry Practice Act that the Department of Managed Health Care encounters in the course of the administration of the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) An optometrist, a registered dispensing optician, an optical company, or a health plan may execute a lease or other written agreement giving rise to a direct or indirect landlord-tenant relationship with an optometrist, if all of the following conditions are contained in a written agreement establishing the landlord-tenant relationship:

(1) (A) The practice shall be owned by the optometrist and in every phase be under the optometrist's exclusive control, including the selection and supervision of optometric staff, the scheduling of patients, the amount of time the optometrist spends with patients, fees charged for optometric products and services, the examination procedures and treatment provided to patients and the optometrist's contracting with managed care organizations.

(B) Subparagraph (A) shall not preclude a lease from including commercially reasonable terms that: (i) require the provision of optometric services at the leased space during certain days and hours, (ii) restrict the leased space from being used for the sale or offer for sale of spectacles, frames, lenses, contact lenses, or other ophthalmic products, except that the optometrist shall be permitted to sell therapeutic ophthalmic products if the registered dispensing optician, health plan, or optical company located on or adjacent to the optometrist's leased space does not offer any substantially similar therapeutic ophthalmic products for sale, (iii) require the optometrist to contract with a health plan network, health plan, or health insurer, or (iv) permit the landlord to directly or indirectly provide furnishings and equipment in the leased space.

(2) The optometrist's records shall be the sole property of the optometrist. Only the optometrist and those persons with written authorization from the optometrist shall have access to the patient records and the examination room, except as otherwise provided by law.

(3) The optometrist's leased space shall be definite and distinct from space occupied by other occupants of the premises, have a sign designating that the leased space is occupied by an independent optometrist or optometrists and be accessible to the optometrist after hours or in the case of an emergency, subject to the facility's general accessibility. This paragraph shall not require a separate entrance to the optometrist's leased space.

(4) All signs and displays shall be separate and distinct from that of the other occupants and shall have the optometrist's name and the word "optometrist" prominently displayed in connection therewith. This paragraph shall not prohibit the optometrist from advertising the optometrist's practice location with reference to other occupants or prohibit the optometrist or registered dispensing optician from advertising their participation in any health plan's network or the health plan's products in which the optometrist or registered dispensing optician participates.

(5) There shall be no signs displayed on any part of the premises or in any advertising indicating that the optometrist is employed or controlled by the registered dispensing optician, health plan or optical company.

(6) Except for a statement that an independent doctor of optometry is located in the leased space, in-store pricing signs and as otherwise permitted by this subdivision, the registered dispensing optician or optical company shall not link its advertising with the optometrist's name, practice, or fees.

(7) Notwithstanding paragraphs (4) and (6), this subdivision shall not preclude a health plan from advertising its health plan products and associated premium costs and any copayments, coinsurance, deductibles, or other forms of cost sharing, or the names and locations of the health plan's providers, including any optometrists or registered dispensing opticians that provide professional services, in compliance with 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).

(8) A health plan that advertises its products and services in accordance with paragraph (7) shall not advertise the optometrist's fees for products and services that are not included in the health plan's contract with the optometrist.

(9) The optometrist shall not be precluded from collecting fees for services that are not included in a health plan's products and services, subject to any patient disclosure requirements contained in the health plan's provider agreement with the optometrist or that are not otherwise prohibited by 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).

(10) The term of the lease shall be no less than one year and shall not require the optometrist to contract exclusively with a health plan. The optometrist may terminate the lease according to the terms of the lease. The landlord may terminate the lease for the following reasons:

(A) The optometrist's failure to maintain a license to practice optometry or the imposition of restrictions, suspension or revocation of the optometrist's license or if the optometrist or the optometrist's employee is or becomes ineligible to participate in state or federal government-funded programs.

(B) Termination of any underlying lease where the optometrist has subleased space, or the optometrist's failure to comply with the underlying lease provisions that are made applicable to the optometrist.

(C) If the health plan is the landlord, the termination of the provider agreement between the health plan and the optometrist, in accordance with the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(D) Other reasons pursuant to the terms of the lease or permitted under the Civil Code.

(11) The landlord shall act in good faith in terminating the lease and in no case shall the landlord terminate the lease for reasons that constitute interference with the practice of optometry.

(12) Lease or rent terms and payments shall not be based on number of eye exams performed, prescriptions written, patient referrals or the sale or promotion of the products of a registered dispensing optician or an optical company.

(13) The landlord shall not terminate the lease solely because of a report, complaint, or allegation filed by the optometrist against the landlord, a registered dispensing optician or a health plan, to the State Board of Optometry or the Department of Managed Health Care or any law enforcement or regulatory agency.

(14) The landlord shall provide the optometrist with written notice of the scheduled expiration date of a lease at least 60 days prior to the scheduled expiration date. This notice obligation shall not affect the ability of either party to terminate the lease pursuant to this section. The landlord may not interfere with an outgoing optometrist's efforts to inform the optometrist's patients, in accordance with customary practice and professional obligations, of the relocation of the optometrist's practice.

(15) The State Board of Optometry may inspect, upon request, an individual lease agreement pursuant to its investigational authority, and if such a request is made, the landlord or tenant, as applicable, shall promptly comply with the request. Failure or refusal to comply with the request for lease agreements within 30 days of receiving the request constitutes unprofessional conduct and is grounds for disciplinary action by the appropriate regulatory agency. This section shall not affect the Department of Managed Health Care's authority to inspect all books and records of a health plan pursuant to Section 1381 of the Health and Safety Code.

Any financial information contained in the lease submitted to a regulatory entity, pursuant to this paragraph, shall be considered confidential trade secret information that is exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(16) This subdivision shall not be applicable to the relationship between any optometrist employee and the employer medical group, or the relationship between a medical group exclusively contracted with a health plan regulated by the Department of Managed Health Care and that health plan.

(e) No registered dispensing optician may have any membership, proprietary interest, coownership, or profit-sharing arrangement either by stock ownership, interlocking directors, trusteeship, mortgage, or trust deed, with an optometrist, except as permitted under this section.

(f) Nothing in this section shall prohibit a person licensed under Chapter 5 (commencing with Section 2000) or its professional corporation from contracting with or employing optometrists, ophthalmologists, or optometric assistants and entering into a contract or landlord tenant relationship with a health plan, an optical company, or a registered dispensing optician, in accordance with Sections 650 and 654 of this code.

(g) Any violation of this section constitutes a misdemeanor as to such person licensed under Chapter 7 (commencing with Section 3000) of this division and as to any and all persons, whether or not so licensed under this division, who participate with such licensed person in a violation of any provision of this section.

(h) (1) Notwithstanding any other law and in addition to any action available to the State Board of Optometry, the State Board of Optometry may issue a citation containing an order of abatement, an order to pay an administrative fine, or both, to an optical company, an optometrist, or a registered dispensing optician for a violation of this section. The administrative fine shall not exceed fifty thousand dollars ($50,000) per investigation. In assessing the amount of the fine, the board shall give due consideration to all of the following:

(A) The gravity of the violation.

(B) The good faith of the cited person or entity.

(C) The history of previous violations of the same or similar nature.

(D) Evidence that the violation was or was not willful.

(E) The extent to which the cited person or entity has cooperated with the board's investigation.

(F) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.

(G) Any other factors as justice may require.

(2) A citation or fine assessment issued pursuant to a citation shall inform the cited person or entity that if a hearing is desired to contest the finding of a violation, that hearing shall be requested by written notice to the board 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.

(3) The board shall adopt regulations to implement a system for the issuance of citations, administrative fines, and orders of abatement authorized by this section. The regulations shall include provisions for both of the following:

(A) The issuance of a citation without an administrative fine.

(B) The opportunity for a cited person or entity to have an informal conference with the executive officer of the board in addition to the hearing described in paragraph (2).

(4) The 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. 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.

(5) Notwithstanding any other 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.

(i) Administrative fines collected pursuant to this section shall be deposited in the Dispensing Opticians Fund. It is the intent of the Legislature that moneys collected as fines and deposited in the fund be used by the board primarily for enforcement purposes.

SEC. 3. Section 1944 of the Business and Professions Code is amended to read:

1944. (a) The committee shall establish by resolution the amount of the fees that relate to the licensing of a registered dental hygienist, a registered dental hygienist in alternative practice, and a registered dental hygienist in extended functions. The fees established by board resolution in effect on June 30, 2009, as they relate to the licensure of registered dental hygienists, registered dental hygienists in alternative practice, and registered dental hygienists in extended functions, shall remain in effect until modified by the committee. The fees are subject to the following limitations:

(1) The application fee for an original license and the fee for issuance of an original license shall not exceed two hundred fifty dollars ($250).

(2) The fee for examination for licensure as a registered dental hygienist shall not exceed the actual cost of the examination.

(3) The fee for examination for licensure as a registered dental hygienist in extended functions shall not exceed the actual cost of the examination.

(4) The fee for examination for licensure as a registered dental hygienist in alternative practice shall not exceed the actual cost of administering the examination.

(5) The biennial renewal fee shall not exceed five hundred dollars ($500).

(6) The delinquency fee shall not exceed one-half of the renewal fee. Any delinquent license may be restored only upon payment of all fees,

including the delinquency fee, and compliance with all other applicable requirements of this article.

(7) The fee for issuance of a duplicate license to replace one that is lost or destroyed, or in the event of a name change, shall not exceed twenty-five dollars ($25) or one-half of the renewal fee, whichever is greater.

(8) The fee for certification of licensure shall not exceed one-half of the renewal fee.

(9) The fee for each curriculum review, feasibility study review, and site evaluation for educational programs for dental hygienists who are not accredited by a committee-approved agency shall not exceed two thousand one hundred dollars ($2,100).

(10) The fee for each review or approval of course requirements for licensure or procedures that require additional training shall not exceed seven hundred fifty dollars ($750).

(11) The initial application and biennial fee for a provider of continuing education shall not exceed five hundred dollars ($500).

(12) The amount of fees payable in connection with permits issued under Section 1962 is as follows:

(A) The initial permit fee is an amount equal to the renewal fee for the applicant's license to practice dental hygiene in effect on the last regular renewal date before the date on which the permit is issued.

(B) If the permit will expire less than one year after its issuance, then the initial permit fee is an amount equal to 50 percent of the renewal fee in effect on the last regular renewal date before the date on which the permit is issued.

(b) The renewal and delinquency fees shall be fixed by the committee by resolution at not more than the current amount of the renewal fee for a license to practice under this article nor less than five dollars ($5).

(c) Fees fixed by the committee by resolution pursuant to this section shall not be subject to the approval of the Office of Administrative Law.

(d) Fees collected pursuant to this section shall be collected by the committee and deposited into the State Dental Hygiene Fund, which is hereby created. All money in this fund shall, upon appropriation by the Legislature in the annual Budget Act, be used to implement this article.

(e) No fees or charges other than those listed in this section shall be levied by the committee in connection with the licensure of registered dental hygienists, registered dental hygienists in alternative practice, or registered dental hygienists in extended functions.

(f) The fee for registration of an extramural dental facility shall not exceed two hundred fifty dollars ($250).

(g) The fee for registration of a mobile dental hygiene unit shall not exceed one hundred fifty dollars ($150).

(h) The biennial renewal fee for a mobile dental hygiene unit shall not exceed two hundred fifty dollars ($250).

(i) The fee for an additional office permit shall not exceed two hundred fifty dollars ($250).

(j) The biennial renewal fee for an additional office as described in Section 1926.4 shall not exceed two hundred fifty dollars ($250).

(k) The initial application and biennial special permit fee is an amount equal to the biennial renewal fee specified in paragraph (6) of subdivision (a).

(*l*) The fees in this section shall not exceed an amount sufficient to cover the reasonable regulatory cost of carrying out this article.

SEC. 4. Section 2546.9 of the Business and Professions Code is repealed.

SEC. 5. Section 2546.9 is added to the Business and Professions Code, to read:

2546.9. The amount of fees prescribed in connection with the registration of nonresident contact lens sellers is that established by the following schedule:

(a) The application fee for a nonresident contact lens seller shall be a minimum of one hundred fifty dollars ($150) and shall not exceed two hundred dollars ($200).

(b) The initial registration fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(c) The renewal fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(d) The delinquency fee shall be a minimum of fifty dollars ($50) and shall not exceed seventy-five dollars ($75).

(e) The fee for replacement of a lost, stolen, or destroyed registration shall be twenty-five dollars ($25).

(f) The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.

(g) The fees collected pursuant to this chapter shall be deposited in the Dispensing Opticians Fund, and shall be available, upon appropriation, to the State Board of Optometry for the purposes of this chapter.

SEC. 6. Section 2565 of the Business and Professions Code is repealed.

SEC. 7. Section 2565 is added to the Business and Professions Code, to read:

2565. The amount of fees prescribed in connection with the registration of dispensing opticians shall be as set forth in this section.

(a) The application fee for registration shall be a minimum of one hundred fifty dollars ($150) and shall not exceed two hundred dollars ($200).

(b) The initial registration fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(c) The renewal fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(d) The delinquency fee shall be a minimum of fifty dollars ($50) and shall not exceed seventy-five dollars ($75).

(e) The fee for replacement of a lost, stolen, or destroyed certificate shall be twenty-five dollars ($25).

(f) The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.

SEC. 8. Section 2566 of the Business and Professions Code is repealed.

SEC. 9. Section 2566 is added to the Business and Professions Code, to read:

2566. The amount of fees prescribed in connection with certificates for contact lens dispensers is as follows:

(a) The application fee for a registered contact lens dispenser shall be a minimum of one hundred fifty dollars ($150) and shall not exceed two hundred dollars ($200).

(b) The initial registration fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(c) The biennial fee for the renewal of certificates shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(d) The delinquency fee shall be a minimum of fifty dollars ($50) and shall not exceed seventy-five dollars ($75).

(e) The division may by regulation provide for a refund of a portion of the application fee to applicants who do not meet the requirements for registration.

(f) The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.

(g) The fee for replacement of a lost, stolen, or destroyed certificate is twenty-five dollars ($25).

SEC. 10. Section 2566.1 of the Business and Professions Code is repealed.

SEC. 11. Section 2566.1 is added to the Business and Professions Code, to read:

2566.1. The amount of fees prescribed in connection with certificates for spectacle lens dispensers shall be as set forth in this section:

(a) The application for registration fee shall be a minimum of one hundred fifty dollars ($150) and shall not exceed two hundred dollars ($200).

(b) The initial registration fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(c) The renewal fee shall be a minimum of two hundred dollars ($200) and shall not exceed three hundred dollars ($300).

(d) The delinquency fee shall be a minimum of fifty dollars ($50) and shall not exceed seventy-five dollars ($75).

(e) The fee for replacement of a lost, stolen, or destroyed certificate is twenty-five dollars ($25).

(f) The State Board of Optometry may periodically revise and fix by regulation the fees specified in subdivisions (a), (b), (c), and (d), and these revised fees shall not exceed the reasonable regulatory cost.

SEC. 12. Section 2733 of the Business and Professions Code is amended to read:

2733. (a) (1) (A) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (k) of Section 2815, the board may issue a temporary license to practice professional nursing, and a temporary certificate to practice as a certified public health nurse for a period of six months from the date of issuance.

(B) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (d) of Section 2838.2, the board may issue a temporary certificate to practice as a certified clinical nurse specialist for a period of six months from the date of issuance.

(C) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (e) of Section 2815.5, the board may issue a temporary certificate to practice as a certified nurse-midwife for a period of six months from the date of issuance.

(D) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (d) of Section 2830.7, the board may issue a temporary certificate to practice as a certified nurse anesthetist for a period of six months from the date of issuance.

(E) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (p) of Section 2815, the board may issue a temporary certificate to practice as a certified nurse practitioner for a period of six months from the date of issuance.

(2) A temporary license or temporary certificate shall terminate upon notice thereof by certified mail, return receipt requested, if it is issued by mistake or if the application for permanent licensure is denied.

(b) Upon written application, the board may reissue a temporary license or temporary certificate to any person who has applied for a regular renewable license pursuant to subdivision (b) of Section 2732.1 and who, in the judgment of the board has been excusably delayed in completing his or her application for or the minimum requirements for a regular renewable license, but the board may not reissue a temporary license or temporary certificate more than twice to any one person.

SEC. 13. Section 2746.53 is added to the Business and Professions Code, to read:

2746.53. The board may charge the applicant a fee to cover all necessary costs to implement Section 2746.51, that shall be not less than four hundred dollars ($400) nor more than one thousand five hundred dollars ($1,500) for an initial application, nor less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000) for an application for renewal. The board may charge a penalty fee for failure to renew a furnishing number within the prescribed time that shall be not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

SEC. 14. Section 2786.5 of the Business and Professions Code is amended to read:

2786.5. (a) An institution of higher education or a private postsecondary school of nursing approved by the board pursuant to subdivision (b) of Section 2786 shall remit to the board for deposit in the Board of Registered Nursing Fund the following fees, in accordance with the following schedule:

(1) The fee for approval of a school of nursing shall be fixed by the board at not less than forty thousand dollars ($40,000) nor more than eighty thousand dollars ($80,000).

(2) The fee for continuing approval of a nursing program established after January 1, 2013, shall be fixed by the board at not less than fifteen thousand dollars ($15,000) nor more than thirty thousand dollars ($30,000).

(3) The processing fee for authorization of a substantive change to an approval of a school of nursing shall be fixed by the board at not less than two thousand five hundred dollars ($2,500) nor more than five thousand dollars ($5,000).

(b) If the board determines that the annual cost of providing oversight and review of a school of nursing, as required by this article, is less than the amount of any fees required to be paid by that institution pursuant to this article, the board may decrease the fees applicable to that institution to an amount that is proportional to the board's costs associated with that institution.

SEC. 15. Section 2811 of the Business and Professions Code is amended to read:

2811. (a) Each person holding a regular renewable license under this chapter, whether in an active or inactive status, shall apply for a renewal of his or her license and pay the biennial renewal fee required by this chapter each two years on or before the last day of the month following the month in which his or her birthday occurs, beginning with the second birthday following the date on which the license was issued, whereupon the board shall renew the license.

(b) Each such license not renewed in accordance with this section shall expire but may within a period of eight years thereafter be reinstated upon payment of the fee required by this chapter and upon submission of such proof of the applicant's qualifications as may be required by the board, except that during such eight-year period no examination shall be required as a condition for the reinstatement of any such expired license which has lapsed solely by reason of nonpayment of the renewal fee. After the expiration of such eight-year period the board may require as a condition of reinstatement that the applicant pass such examination as it deems necessary to determine his present fitness to resume the practice of professional nursing.

(c) A license in an inactive status may be restored to an active status if the licensee meets the continuing education standards of Section 2811.5.

SEC. 16. Section 2811.5 of the Business and Professions Code is amended to read:

2811.5. (a) Each person renewing his or her license under Section 2811 shall submit proof satisfactory to the board that, during the preceding two-year period, he or she has been informed of the developments in the registered nurse field or in any special area of practice engaged in by the licensee, occurring since the last renewal thereof, either by pursuing a course or courses of continuing education in the registered nurse field or relevant to the practice of the licensee, and approved by the board, or by other means deemed equivalent by the board.

(b) For purposes of this section, the board shall, by regulation, establish standards for continuing education. The standards shall be established in a manner to ensure that a variety of alternative forms of continuing education are available to licensees, including, but not limited to, academic studies, in-service education, institutes, seminars, lectures, conferences, workshops, extension studies, and home study programs. The standards shall take cognizance of specialized areas of practice, and content shall be relevant to the practice of nursing and shall be related to the scientific knowledge or technical skills required for the practice of nursing or be related to direct or indirect patient or client care. The continuing education standards established by the board shall not exceed 30 hours of direct participation in a course or courses approved by the board, or its equivalent in the units of measure adopted by the board.

(c) The board shall audit continuing education providers at least once every five years to ensure adherence to regulatory requirements, and shall withhold or rescind approval from any provider that is in violation of the regulatory requirements.

(d) The board shall encourage continuing education in spousal or partner abuse detection and treatment. In the event the board establishes a requirement for continuing education coursework in spousal or partner abuse detection or treatment, that requirement shall be met by each licensee within no more than four years from the date the requirement is imposed.

(e) In establishing standards for continuing education, the board shall consider including a course in the special care needs of individuals and their families facing end-of-life issues, including, but not limited to, all of the following:

(1) Pain and symptom management.

(2) The psycho-social dynamics of death.

(3) Dying and bereavement.

(4) Hospice care.

(f) In establishing standards for continuing education, the board may include a course on pain management.

(g) This section shall not apply to licensees during the first two years immediately following their initial licensure in California or any other governmental jurisdiction.

(h) The board may, in accordance with the intent of this section, make exceptions from continuing education requirements for licensees residing in another state or country, or for reasons of health, military service, or other good cause.

SEC. 17. Section 2815 of the Business and Professions Code is amended to read:

2815. Subject to the provisions of Section 128.5, the amount of the fees prescribed by this chapter in connection with the issuance of licenses for registered nurses under its provisions is that fixed by the following schedule:

(a) (1) The fee to be paid upon the filing by a graduate of an approved school of nursing in this state of an application for a licensure by examination shall be fixed by the board at not less than three hundred dollars ($300) nor more than one thousand dollars ($1,000).

(2) The fee to be paid upon the filing by a graduate of a school of nursing in another state, district, or territory of the United States of an application for a licensure by examination shall be fixed by the board at not less than three hundred fifty dollars ($350) nor more than one thousand dollars ($1,000).

(3) The fee to be paid upon the filing by a graduate of a school of nursing in another country of an application for a licensure by examination shall be fixed by the board at not less than seven hundred fifty dollars ($750) nor more than one thousand five hundred dollars ($1,500).

(4) The fee to be paid upon the filing of an application for licensure by a repeat examination shall be fixed by the board at not less than two hundred fifty dollars ($250) and not more than one thousand dollars ($1,000).

(b) The fee to be paid for taking each examination shall be the actual cost to purchase an examination from a vendor approved by the board.

(c) (1) The fee to be paid for application by a person who is licensed or registered as a nurse in another state, district, or territory of the United States for licensure by endorsement shall be fixed by the board at not less than three hundred fifty dollars ($350) nor more than one thousand dollars ($1,000).

(2) The fee to be paid for application by a person who is licensed or registered as a nurse in another country for licensure by endorsement shall be fixed by the board at not less than seven hundred fifty dollars ($750) nor more than one thousand five hundred dollars ($1,500).

(d) (1) The biennial fee to be paid upon the filing of an application for renewal of the license shall be not less than one hundred eighty dollars ($180) nor more than seven hundred fifty dollars ($750). In addition, an assessment of ten dollars ($10) shall be collected and credited to the Registered Nurse Education Fund, pursuant to Section 2815.1.

(2) The fee to be paid upon the filing of an application for reinstatement pursuant to subdivision (b) of Section 2811 shall be not less than three hundred fifty dollars ($350) nor more than one thousand dollars ($1,000).

(e) The penalty fee for failure to renew a license within the prescribed time shall be fixed by the board at not more than 50 percent of the regular renewal fee, but not less than ninety dollars ($90) nor more than three hundred seventy-five dollars ($375).

(f) The fee to be paid for approval of a continuing education provider shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand dollars ($1,000).

(g) The biennial fee to be paid upon the filing of an application for renewal of provider approval shall be fixed by the board at not less than seven hundred fifty dollars ($750) nor more than one thousand dollars ($1,000).

(h) The penalty fee for failure to renew provider approval within the prescribed time shall be fixed at not more than 50 percent of the regular renewal fee, but not less than one hundred twenty-five dollars ($125) nor more than five hundred dollars ($500).

(i) The penalty for submitting insufficient funds or fictitious check, draft or order on any bank or depository for payment of any fee to the board shall be fixed at not less than fifteen dollars ($15) nor more than thirty dollars ($30).

(j) The fee to be paid for an interim permit shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred fifty dollars ($250).

(k) The fee to be paid for a temporary license shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred fifty dollars ($250).

(*l*) The fee to be paid for processing endorsement papers to other states shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred dollars ($200).

(m) The fee to be paid for a certified copy of a school transcript shall be fixed by the board at not less than fifty dollars ($50) nor more than one hundred dollars ($100).

(n) (1) The fee to be paid for a duplicate pocket license shall be fixed by the board at not less than fifty dollars ($50) nor more than seventy-five dollars ($75).

(2) The fee to be paid for a duplicate wall certificate shall be fixed by the board at not less than sixty dollars ($60) nor more than one hundred dollars ($100).

(o) (1) The fee to be paid by a registered nurse for an evaluation of his or her qualifications to use the title “nurse practitioner” shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand five hundred dollars ($1,500).

(2) The fee to be paid by a registered nurse for a temporary certificate to practice as a nurse practitioner shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than five hundred dollars ($500).

(3) The fee to be paid upon the filing of an application for renewal of a certificate to practice as a nurse practitioner shall be not less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000).

(4) The penalty fee for failure to renew a certificate to practice as a nurse practitioner within the prescribed time shall be not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(p) The fee to be paid by a registered nurse for listing as a “psychiatric mental health nurse” shall be fixed by the board at not less than three hundred fifty dollars ($350) nor more than seven hundred fifty dollars ($750).

(q) The fee to be paid for duplicate National Council Licensure Examination for registered nurses (NCLEX-RN) examination results shall be not less than sixty dollars ($60) nor more than one hundred dollars ($100).

(r) The fee to be paid for a letter certifying a license shall be not less than twenty dollars ($20) nor more than thirty dollars ($30).

No further fee shall be required for a license or a renewal thereof other than as prescribed by this chapter.

SEC. 18. Section 2815.5 of the Business and Professions Code is amended to read:

2815.5. The amount of the fees prescribed by this chapter in connection with the issuance of certificates as nurse-midwives is that fixed by the following schedule:

(a) The fee to be paid upon the filing of an application for a certificate shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand five hundred dollars ($1,500).

(b) The biennial fee to be paid upon the application for a renewal of a certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000).

(c) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(d) The fee to be paid upon the filing of an application for the nurse-midwife equivalency examination shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred dollars ($200).

(e) The fee to be paid for a temporary certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than five hundred dollars ($500).

SEC. 19. Section 2816 of the Business and Professions Code is amended to read:

2816. The nonrefundable fee to be paid by a registered nurse for an evaluation of his or her qualifications to use the title “public health nurse” shall be equal to the fees set out in subdivision (o) of Section 2815. The fee to be paid upon the application for renewal of the certificate to practice as a public health nurse shall be fixed by the board at not less than one hundred twenty-five dollars ($125) and not more than five hundred dollars ($500). All fees payable under this section shall be collected by and paid to the Registered Nursing Fund. It is the intention of the Legislature that the costs of carrying out the purposes of this article shall be covered by the revenue collected pursuant to this section.

SEC. 20. Section 2830.7 of the Business and Professions Code is amended to read:

2830.7. The amount of the fees prescribed by this chapter in connection with the issuance of certificates as nurse anesthetists is that fixed by the following schedule:

(a) The fee to be paid upon the filing of an application for a certificate shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand five hundred dollars ($1,500).

(b) The biennial fee to be paid upon the application for a renewal of a certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000).

(c) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(d) The fee to be paid for a temporary certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than five hundred dollars ($500).

SEC. 21. Section 2836.3 of the Business and Professions Code is amended to read:

2836.3. (a) The furnishing of drugs or devices by nurse practitioners is conditional on issuance by the board of a number to the nurse applicant who has successfully completed the requirements of subdivision (g) of Section 2836.1. The number shall be included on all transmittals of orders for drugs or devices by the nurse practitioner. The board shall make the list of numbers issued available to the Board of Pharmacy. The board may charge the applicant a fee to cover all necessary costs to implement this section, that shall be not less than four hundred dollars ($400) nor more than one thousand five hundred dollars ($1,500) for an initial application, nor less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000) for an application for renewal. The board may charge a penalty fee for failure to renew a furnishing number within the prescribed time that shall be not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(b) The number shall be renewable at the time of the applicant's registered nurse license renewal.

(c) The board may revoke, suspend, or deny issuance of the numbers for incompetence or gross negligence in the performance of functions specified in Sections 2836.1 and 2836.2.

SEC. 22. Section 2838.2 of the Business and Professions Code is amended to read:

2838.2. (a) A clinical nurse specialist is a registered nurse with advanced education, who participates in expert clinical practice, education, research, consultation, and clinical leadership as the major components of his or her role.

(b) The board may establish categories of clinical nurse specialists and the standards required to be met for nurses to hold themselves out as clinical nurse specialists in each category. The standards shall take into account the types of advanced levels of nursing practice that are or may be performed and the clinical and didactic education, experience, or both needed to practice safety at those levels. In setting the standards, the board shall consult with clinical nurse specialists, physicians and surgeons appointed by the Medical

Board of California with expertise with clinical nurse specialists, and health care organizations that utilize clinical nurse specialists.

(c) A registered nurse who meets one of the following requirements may apply to become a clinical nurse specialist:

(1) Possession of a master's degree in a clinical field of nursing.

(2) Possession of a master's degree in a clinical field related to nursing with coursework in the components referred to in subdivision (a).

(3) On or before July 1, 1998, meets the following requirements:

(A) Current licensure as a registered nurse.

(B) Performs the role of a clinical nurse specialist as described in subdivision (a).

(C) Meets any other criteria established by the board.

(d) (1) A nonrefundable fee of not less than five hundred dollars ($500), but not to exceed one thousand five hundred dollars ($1,500) shall be paid by a registered nurse applying to be a clinical nurse specialist for the evaluation of his or her qualifications to use the title "clinical nurse specialist."

(2) The fee to be paid for a temporary certificate to practice as a clinical nurse specialist shall be not less than thirty dollars ($30) nor more than fifty dollars ($50).

(3) A biennial renewal fee shall be paid upon submission of an application to renew the clinical nurse specialist certificate and shall be established by the board at no less than one hundred fifty dollars ($150) and no more than one thousand dollars ($1,000).

(4) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(5) The fees authorized by this subdivision shall not exceed the amount necessary to cover the costs to the board to administer this section.

SEC. 23. Section 3030 is added to the Business and Professions Code, to read:

3030. The board may at any time inspect the premises in which optometry is being practiced or in which spectacle or contact lenses are fitted or dispensed. The board's inspection authority does not extend to premises that are not registered with the board. Nothing in this section shall be construed to affect the board's ability to investigate alleged unlicensed activity or to inspect premises for which registration has lapsed or is delinquent.

SEC. 24. Section 4128.2 of the Business and Professions Code is amended to read:

4128.2. (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).

SEC. 25. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be 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.

SEC. 26. Section 4400 is added to the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be 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.

SEC. 27. Section 4830 of the Business and Professions Code is amended to read:

4830. (a) This chapter does not apply to:

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.

(2) Veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case. The California licensed veterinarian shall maintain a valid veterinarian-client-patient relationship. The veterinarian providing the assistance shall not establish a veterinarian-client-patient relationship with the client by attending the case or at a future time and shall not practice veterinary medicine, open an office, appoint a place to meet patients, communicate with clients who reside within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient that is located within this state.

(3) Veterinarians called into the state by a law enforcement agency or animal control agency pursuant to subdivision (b).

(4) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational

programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

(5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

(6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

(A) The temporary shelter facility is established only for the purpose of the investigation.

(B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.

(C) The temporary shelter facility complies with Section 4854.

(D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.

(E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law

enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.

(c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.

SEC. 28. Section 4999 of the Business and Professions Code is amended to read:

4999. "Telephone medical advice service" means any business entity that employs, or contracts or subcontracts, directly or indirectly, with, the full-time equivalent of five or more persons functioning as health care professionals, whose primary function is to provide telephone medical advice, that provides telephone medical advice services to a patient at a California address. "Telephone medical advice service" does not include a medical group that operates in multiple locations in California if no more than five full-time equivalent persons at any one location perform telephone medical advice services and those persons limit the telephone medical advice services to patients being treated at that location.

SEC. 29. Section 4999.1 of the Business and Professions Code is repealed.

SEC. 30. Section 4999.2 of the Business and Professions Code is amended to read:

4999.2. A telephone medical advice service shall be responsible for complying with the following requirements:

(a) (1) Ensuring that all health care professionals who provide medical advice services are appropriately licensed, certified, or registered as a physician and surgeon pursuant to Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act, as a dentist, dental hygienist, dental hygienist in alternative practice, or dental hygienist in extended functions pursuant to Chapter 4 (commencing with Section 1600), as an occupational therapist pursuant to Chapter 5.6 (commencing with Section 2570), as a registered nurse pursuant to Chapter 6 (commencing with Section 2700), as a psychologist pursuant to Chapter 6.6 (commencing with Section 2900), as a naturopathic doctor pursuant to Chapter 8.2 (commencing with Section 3610), as a marriage and family therapist pursuant to Chapter 13 (commencing with Section 4980), as a licensed clinical social worker pursuant to Chapter 14 (commencing with Section 4991), as a licensed professional clinical counselor pursuant to Chapter 16 (commencing with Section 4999.10), as an optometrist pursuant to Chapter 7 (commencing with Section 3000), or as a chiropractor pursuant to the Chiropractic Initiative Act, and operating consistent with the laws governing their respective scopes of practice in the state within which they provide telephone medical advice services, except as provided in subdivision (b).

(2) Ensuring that all health care professionals who provide telephone medical advice services from an out-of-state location, as identified in paragraph (1), are licensed, registered, or certified in the state within which

they are providing the telephone medical advice services and are operating consistent with the laws governing their respective scopes of practice.

(b) Ensuring that the telephone medical advice provided is consistent with good professional practice.

(c) Maintaining records of telephone medical advice services, including records of complaints, provided to patients in California for a period of at least five years.

(d) Ensuring that no staff member uses a title or designation when speaking to an enrollee, subscriber, or consumer that may cause a reasonable person to believe that the staff member is a licensed, certified, or registered health care professional described in paragraph (1) of subdivision (a), unless the staff member is a licensed, certified, or registered professional.

(e) Complying with all directions and requests for information made by the department.

(f) Notifying the department within 30 days of any change of name, physical location, mailing address, or telephone number of any business, owner, partner, corporate officer, or agent for service of process in California, together with copies of all resolutions or other written communications that substantiate these changes.

SEC. 31. Section 4999.3 of the Business and Professions Code is repealed.

SEC. 32. Section 4999.4 of the Business and Professions Code is repealed.

SEC. 33. Section 4999.5 of the Business and Professions Code is repealed.

SEC. 34. Section 4999.5 is added to the Business and Professions Code, to read:

4999.5. The respective healing arts licensing boards shall be responsible for enforcing this chapter and any other laws and regulations affecting California licensed health care professionals providing telephone medical advice services.

SEC. 35. Section 4999.6 of the Business and Professions Code is repealed.

SEC. 36. Section 7137 of the Business and Professions Code is amended to read:

7137. The board shall set fees by regulation. These fees shall not exceed the following schedule:

(a) The application fee for an original license in a single classification shall not be more than three hundred dollars ($300).

The application fee for each additional classification applied for in connection with an original license shall not be more than seventy-five dollars ($75).

The application fee for each additional classification pursuant to Section 7059 shall not be more than seventy-five dollars ($75).

The application fee to replace a responsible managing officer, responsible managing manager, responsible managing member, or responsible managing

employee pursuant to Section 7068.2 shall not be more than seventy-five dollars ($75).

(b) The fee for rescheduling an examination for an applicant who has applied for an original license, additional classification, a change of responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee, or for an asbestos certification or hazardous substance removal certification, shall not be more than sixty dollars ($60).

(c) The fee for scheduling or rescheduling an examination for a licensee who is required to take the examination as a condition of probation shall not be more than sixty dollars ($60).

(d) The initial license fee for an active or inactive license shall not be more than one hundred eighty dollars ($180).

(e) The renewal fee for an active license shall not be more than three hundred sixty dollars ($360).

The renewal fee for an inactive license shall not be more than one hundred eighty dollars ($180).

(f) The delinquency fee is an amount equal to 50 percent of the renewal fee, if the license is renewed after its expiration.

(g) The registration fee for a home improvement salesperson shall not be more than seventy-five dollars ($75).

(h) The renewal fee for a home improvement salesperson registration shall not be more than seventy-five dollars ($75).

(i) The application fee for an asbestos certification examination shall not be more than seventy-five dollars ($75).

(j) The application fee for a hazardous substance removal or remedial action certification examination shall not be more than seventy-five dollars ($75).

(k) In addition to any other fees charged to C-10 and C-7 contractors, the board may charge a fee not to exceed twenty dollars ($20), which shall be used by the board to enforce provisions of the Labor Code related to electrician certification.

(*l*) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

SEC. 37. Section 7137 is added to the Business and Professions Code, to read:

7137. The board may set fees by regulation. These fees shall be set according to the following schedule:

(a) (1) The application fee for an original license in a single classification shall be three hundred thirty dollars ($330) and may be increased to not more than three hundred seventy-five dollars ($375).

(2) The application fee for each additional classification applied for in connection with an original license shall not be more than eighty-five dollars ($85).

(3) The application fee for each additional classification pursuant to Section 7059 shall be one hundred fifty dollars ($150) and may be increased to not more than one hundred seventy-five dollars ($175).

(4) The application fee to replace a responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee pursuant to Section 7068.2 shall be one hundred fifty dollars ($150) and may be increased to not more than one hundred seventy-five dollars ($175).

(5) The application fee to add personnel, other than a qualifying individual, to an existing license shall be one hundred dollars ($100) and may be increased to not more than one hundred fifteen dollars ($115).

(b) The fee for rescheduling an examination for an applicant who has applied for an original license, additional classification, a change of responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee, or for an asbestos certification or hazardous substance removal certification, shall not be more than seventy dollars ($70).

(c) The fee for scheduling or rescheduling an examination for a licensee who is required to take the examination as a condition of probation shall not be more than seventy dollars ($70).

(d) The initial license fee for an active or inactive license shall be two hundred dollars ($200) and may be increased to not more than two hundred twenty-five dollars ($225).

(e) (1) The renewal fee for an active license shall be four hundred dollars ($400) and may be increased to not more than four hundred fifty dollars ($450).

(2) The renewal fee for an inactive license shall be two hundred dollars ($200) and may be increased to not more than two hundred twenty-five dollars ($225).

(f) The delinquency fee is an amount equal to 50 percent of the renewal fee, if the license is renewed after its expiration.

(g) The registration fee for a home improvement salesperson shall be eighty-three dollars ($83) and may be increased to not more than ninety-five dollars ($95).

(h) The renewal fee for a home improvement salesperson registration shall be eighty-three dollars ($83) and may be increased to not more than ninety-five dollars ($95).

(i) The application fee for an asbestos certification examination shall be eighty-three dollars ($83) and may be increased to not more than ninety-five dollars ($95).

(j) The application fee for a hazardous substance removal or remedial action certification examination shall be eighty-three dollars ($83) and may be increased to not more than ninety-five dollars ($95).

(k) In addition to any other fees charged to C-10 and C-7 contractors, the board may charge a fee not to exceed twenty dollars ($20), which shall be used by the board to enforce provisions of the Labor Code related to electrician certification.

(*l*) The board shall, by regulation, establish criteria for the approval of expedited processing of applications. Approved expedited processing of

applications for licensure or registration, as required by other provisions of law, shall not be subject to this subdivision.

(m) This section shall become operative on July 1, 2017.

SEC. 38. Section 7153.3 of the Business and Professions Code is amended to read:

7153.3. (a) To renew a home improvement salesperson registration, which has not expired, the registrant shall before the time at which the registration would otherwise expire, apply for renewal on a form prescribed by the registrar and pay a renewal fee prescribed by this chapter. Renewal of an unexpired registration shall continue the registration in effect for the two-year period following the expiration date of the registration, when it shall expire if it is not again renewed.

(b) An application for renewal of registration is delinquent if the application is not postmarked or received via electronic transmission as authorized by Section 7156.6 by the date on which the registration would otherwise expire. A registration may, however, still be renewed at any time within three years after its expiration upon the filing of an application for renewal on a form prescribed by the registrar and the payment of the renewal fee prescribed by this chapter and a delinquent renewal penalty in the amount of twenty-five dollars ($25). If a registration is not renewed within three years, the person shall make a new application for registration pursuant to Section 7153.1.

(c) The registrar may refuse to renew a registration for failure by the registrant to complete the application for renewal of registration. If a registrant fails to return the application rejected for insufficiency or incompleteness within 90 days from the original date of rejection, the application and fee shall be deemed abandoned. Any application abandoned may not be reinstated. However, the person may file a new application for registration pursuant to Section 7153.1.

The registrar may review and accept the petition of a person who disputes the abandonment of his or her renewal application upon a showing of good cause. This petition shall be received within 90 days of the date the application for renewal is deemed abandoned.

(d) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

SEC. 39. Section 7153.3 is added to the Business and Professions Code, to read:

7153.3. (a) To renew a home improvement salesperson registration, which has not expired, the registrant shall before the time at which the registration would otherwise expire, apply for renewal on a form prescribed by the registrar and pay a renewal fee prescribed by this chapter. Renewal of an unexpired registration shall continue the registration in effect for the two-year period following the expiration date of the registration, when it shall expire if it is not again renewed.

(b) An application for renewal of registration is delinquent if the application is not postmarked or received via electronic transmission as authorized by Section 7156.6 by the date on which the registration would

otherwise expire. A registration may, however, still be renewed at any time within three years after its expiration upon the filing of an application for renewal on a form prescribed by the registrar and the payment of the renewal fee prescribed by this chapter and a delinquent renewal penalty equal to 50 percent of the renewal fee. If a registration is not renewed within three years, the person shall make a new application for registration pursuant to Section 7153.1.

(c) (1) The registrar may refuse to renew a registration for failure by the registrant to complete the application for renewal of registration. If a registrant fails to return the application rejected for insufficiency or incompleteness within 90 days from the original date of rejection, the application and fee shall be deemed abandoned. Any application abandoned may not be reinstated. However, the person may file a new application for registration pursuant to Section 7153.1.

(2) The registrar may review and accept the petition of a person who disputes the abandonment of his or her renewal application upon a showing of good cause. This petition shall be received within 90 days of the date the application for renewal is deemed abandoned.

(d) This section shall become operative on July 1, 2017.

SEC. 40. Section 8516 of the Business and Professions Code is amended to read:

8516. (a) This section, and Section 8519, apply only to wood destroying pests or organisms.

(b) A registered company or licensee shall not commence work on a contract, or sign, issue, or deliver any documents expressing an opinion or statement relating to the absence or presence of wood destroying pests or organisms until an inspection has been made by a licensed Branch 3 field representative or operator employed by a registered company, except as provided in Section 8519.5. The address of each property inspected or upon which work is completed shall be reported on a form prescribed by the board and shall be filed with the board no later than 10 business days after the commencement of an inspection or upon completed work.

Every property inspected pursuant to this subdivision or Section 8518 shall be assessed a filing fee pursuant to Section 8674.

Failure of a registered company to report and file with the board the address of any property inspected or work completed pursuant to Section 8518 or this section is grounds for disciplinary action and shall subject the registered company to a fine of not more than two thousand five hundred dollars ($2,500). The address of an inspection report prepared for use by an attorney for litigation purposes shall not be required to be reported to the board and shall not be assessed a filing fee.

A written inspection report conforming to this section and a form approved by the board shall be prepared and delivered to the person requesting the inspection and the property owner, or to the property owner's designated agent, within 10 business days from the start of the inspection, except that an inspection report prepared for use by an attorney for litigation purposes is not required to be reported to the board or the property owner. An

inspection report may be a complete, limited, supplemental, or reinspection report, as defined by Section 1993 of Title 16 of the California Code of Regulations. The report shall be delivered before work is commenced on any property. The registered company shall retain for three years all inspection reports, field notes, and activity forms.

Reports shall be made available for inspection and reproduction to the executive officer of the board or his or her duly authorized representative during business hours. All inspection reports or copies thereof shall be submitted to the board upon demand within two business days. The following shall be set forth in the report:

(1) The start date of the inspection and the name of the licensed field representative or operator making the inspection.

(2) The name and address of the person or firm ordering the report.

(3) The name and address of the property owner and any person who is a party in interest.

(4) The address or location of the property.

(5) A general description of the building or premises inspected.

(6) A foundation diagram or sketch of the structure or structures or portions of the structure or structures inspected, including the approximate location of any infested or infected areas evident, and the parts of the structure where conditions that would ordinarily subject those parts to attack by wood destroying pests or organisms exist. Reporting of the infested or infected wood members, or parts of the structure identified, shall be listed in the inspection report to clearly identify them, as is typical in standard construction components, including, but not limited to, siding, studs, rafters, floor joists, fascia, subfloor, sheathing, and trim boards.

(7) Information regarding the substructure, foundation walls and footings, porches, patios and steps, air vents, abutments, attic spaces, roof framing that includes the eaves, rafters, fascias, exposed timbers, exposed sheathing, ceiling joists, and attic walls, or other parts subject to attack by wood destroying pests or organisms. Conditions usually deemed likely to lead to infestation or infection, such as earth-wood contacts, excessive cellulose debris, faulty grade levels, excessive moisture conditions, evidence of roof leaks, and insufficient ventilation are to be reported.

(8) One of the following statements, as appropriate, printed in bold type:

(A) The exterior surface of the roof was not inspected. If you want the water tightness of the roof determined, you should contact a roofing contractor who is licensed by the Contractors' State License Board.

(B) The exterior surface of the roof was inspected to determine whether or not wood destroying pests or organisms are present.

(9) Indication or description of any areas that are inaccessible or not inspected with recommendation for further inspection if practicable. If, after the report has been made in compliance with this section, authority is given later to open inaccessible areas, a supplemental report on conditions in these areas shall be made.

(10) Recommendations for corrective measures.

(11) Information regarding the pesticide or pesticides to be used for their control or prevention as set forth in subdivision (a) of Section 8538.

(12) The inspection report shall clearly disclose that if requested by the person ordering the original report, a reinspection of the structure will be performed if an estimate or bid for making repairs was given with the original inspection report, or thereafter.

An estimate or bid shall be given separately allocating the costs to perform each and every recommendation for corrective measures as specified in subdivision (c) with the original inspection report if the person who ordered the original inspection report so requests, and if the registered company is regularly in the business of performing each corrective measure.

If no estimate or bid was given with the original inspection report, or thereafter, then the registered company shall not be required to perform a reinspection.

A reinspection shall be an inspection of those items previously listed on an original report to determine if the recommendations have been completed. Each reinspection shall be reported on an original inspection report form and shall be labeled "Reinspection." Each reinspection shall also identify the original report by date.

After four months from an original inspection, all inspections shall be original inspections and not reinspections.

Any reinspection shall be performed for not more than the price of the registered company's original inspection price and shall be completed within 10 business days after a reinspection has been ordered.

(13) The inspection report shall contain the following statement, printed in boldface type:

"NOTICE: Reports on this structure prepared by various registered companies should list the same findings (i.e. termite infestations, termite damage, fungus damage, etc.). However, recommendations to correct these findings may vary from company to company. You have a right to seek a second opinion from another company."

(c) At the time a report is ordered, the registered company or licensee shall inform the person or entity ordering the report, that a separate report is available pursuant to this subdivision. If a separate report is requested at the time the inspection report is ordered, the registered company or licensee shall separately identify on the report each recommendation for corrective measures as follows:

(1) The infestation or infection that is evident.

(2) The conditions that are present that are deemed likely to lead to infestation or infection.

If a registered company or licensee fails to inform as required by this subdivision and a dispute arises, or if any other dispute arises as to whether this subdivision has been complied with, a separate report shall be provided within 24 hours of the request but, in no event, later than the next business day, and at no additional cost.

(d) When a corrective condition is identified, either as paragraph (1) or (2) of subdivision (c), and the property owner or the property owner's designated agent chooses not to correct those conditions, the registered company or licensee shall not be liable for damages resulting from a failure to correct those conditions or subject to any disciplinary action by the board. Nothing in this subdivision, however, shall relieve a registered company or a licensee of any liability resulting from negligence, fraud, dishonest dealing, other violations pursuant to this chapter, or contractual obligations between the registered company or licensee and the responsible parties.

(e) The inspection report form prescribed by the board shall separately identify the infestation or infection that is evident and the conditions that are present that are deemed likely to lead to infestation or infection. If a separate form is requested, the form shall explain the infestation or infection that is evident and the conditions that are present that are deemed likely to lead to infestation or infection and the difference between those conditions. In no event, however, shall conditions deemed likely to lead to infestation or infection be characterized as actual "defects" or as actual "active" infestations or infections or in need of correction as a precondition to issuing a certification pursuant to Section 8519.

(f) The report and any contract entered into shall also state specifically when any guarantee for the work is made, and if so, the specific terms of the guarantee and the period of time for which the guarantee shall be in effect. If a guarantee extends beyond three years, the registered company shall maintain all original inspection reports, field notes, activity forms, and notices of completion for the duration of the guarantee period and for one year after the guarantee expires.

(g) For purposes of this section, "control service agreement" means an agreement, including extended warranties, to have a licensee conduct over a period of time regular inspections and other activities related to the control or eradication of wood destroying pests and organisms. Under a control service agreement a registered company shall refer to the original report and contract in a manner as to identify them clearly, and the report shall be assumed to be a true report of conditions as originally issued, except it may be modified after a control service inspection. A registered company is not required to issue a report as outlined in paragraphs (1) to (11), inclusive, of subdivision (b) after each control service inspection. If after control service inspection, no modification of the original report is made in writing, then it will be assumed that conditions are as originally reported. A control service contract shall state specifically the particular wood destroying pests or organisms and the portions of the buildings or structures covered by the contract.

(h) A registered company or licensee may enter into and maintain a control service agreement provided the following requirements are met:

(1) The control service agreement shall be in writing, signed by both parties, and shall specifically include the following:

(A) The wood destroying pests and organisms covered by the control service agreement.

(B) Any wood destroying pest or organism that is not covered must be specifically listed.

(C) The type and manner of treatment to be used to correct the infestations or infections.

(D) The structures or buildings, or portions thereof, covered by the agreement, including a statement specifying whether the coverage for purposes of periodic inspections is limited or full. Any exclusions from those described in the original report must be specifically listed.

(E) A reference to the original inspection report.

(F) The frequency of the inspections to be provided, the fee to be charged for each renewal, and the duration of the agreement.

(G) Whether the fee includes structural repairs.

(H) If the services provided are guaranteed, and, if so, the terms of the guarantee.

(I) A statement that all corrections of infestations or infections covered by the control service agreement shall be completed within six months of discovery, unless otherwise agreed to in writing by both parties.

(2) The original inspection report, the control service agreement, and completion report shall be maintained for three years after the cancellation of the control service agreement.

(3) Inspections made pursuant to a control service agreement shall be conducted by a Branch 3 licensee. Section 8506.1 does not modify this provision.

(4) A full inspection of the property covered by the control service agreement shall be conducted and a report filed pursuant to subdivision (b) at least once every three years from the date that the agreement was entered into, unless the consumer cancels the contract within three years from the date the agreement was entered into.

(5) Under a control service agreement, a written report shall be required for the correction of any infestation or infection unless all of the following conditions are met:

(A) The infestation or infection has been previously reported.

(B) The infestation or infection is covered by the control service agreement.

(C) There is no additional charge for correcting the infestation or infection.

(D) Correction of the infestation or infection takes place within 45 days of its discovery.

(E) Correction of the infestation or infection does not include fumigation.

(6) All notice requirements pursuant to Section 8538 shall apply to all pesticide treatments conducted under control service agreements.

(i) All work recommended by a registered company, where an estimate or bid for making repairs was given with the original inspection report, or thereafter, shall be recorded on this report or a separate work agreement and shall specify a price for each recommendation. This information shall be provided to the person requesting the inspection, and shall be retained by the registered company with the inspection report copy for three years.

SEC. 41. Section 8518 of the Business and Professions Code is amended to read:

8518. (a) When a registered company completes work under a contract, it shall prepare, on a form prescribed by the board, a notice of work completed and not completed, and shall furnish that notice to the owner of the property or the owner's agent within 10 business days after completing the work. The notice shall include a statement of the cost of the completed work and estimated cost of work not completed.

(b) The address of each property inspected or upon which work was completed shall be reported on a form prescribed by the board and shall be filed with the board no later than 10 business days after completed work.

(c) A filing fee shall be assessed pursuant to Section 8674 for every property upon which work is completed.

(d) Failure of a registered company to report and file with the board the address of any property upon which work was completed pursuant to subdivision (b) of Section 8516 or this section is grounds for disciplinary action and shall subject the registered company to a fine of not more than two thousand five hundred dollars ($2,500).

(e) The registered company shall retain for three years all original notices of work completed, work not completed, and activity forms.

(f) Notices of work completed and not completed shall be made available for inspection and reproduction to the executive officer of the board or his or her duly authorized representative during business hours. Original notices of work completed or not completed or copies thereof shall be submitted to the board upon request within two business days.

(g) This section shall only apply to work relating to wood destroying pests or organisms.

SEC. 42. Section 1348.8 of the Health and Safety Code is amended to read:

1348.8. (a) A health care service plan that provides, operates, or contracts for telephone medical advice services to its enrollees and subscribers shall do all of the following:

(1) Ensure that the in-state or out-of-state telephone medical advice service complies with the requirements of Chapter 15 (commencing with Section 4999) of Division 2 of the Business and Professions Code.

(2) Ensure that the staff providing telephone medical advice services for the in-state or out-of-state telephone medical advice service are licensed as follows:

(A) For full service health care service plans, the staff hold a valid California license as a registered nurse or a valid license in the state within which they provide telephone medical advice services as a physician and surgeon or physician assistant, and are operating in compliance with the laws governing their respective scopes of practice.

(B) (i) For specialized health care service plans providing, operating, or contracting with a telephone medical advice service in California, the staff shall be appropriately licensed, registered, or certified as a dentist pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Business

and Professions Code, as a dental hygienist pursuant to Article 7 (commencing with Section 1740) of Chapter 4 of Division 2 of the Business and Professions Code, as a physician and surgeon pursuant to Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act, as a registered nurse pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, as a psychologist pursuant to Chapter 6.6 (commencing with Section 2900) of Division 2 of the Business and Professions Code, as an optometrist pursuant to Chapter 7 (commencing with Section 3000) of Division 2 of the Business and Professions Code, as a marriage and family therapist pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code, as a licensed clinical social worker pursuant to Chapter 14 (commencing with Section 4991) of Division 2 of the Business and Professions Code, as a professional clinical counselor pursuant to Chapter 16 (commencing with Section 4999.10) of Division 2 of the Business and Professions Code, or as a chiropractor pursuant to the Chiropractic Initiative Act, and operating in compliance with the laws governing their respective scopes of practice.

(ii) For specialized health care service plans providing, operating, or contracting with an out-of-state telephone medical advice service, the staff shall be health care professionals, as identified in clause (i), who are licensed, registered, or certified in the state within which they are providing the telephone medical advice services and are operating in compliance with the laws governing their respective scopes of practice. All registered nurses providing telephone medical advice services to both in-state and out-of-state business entities registered pursuant to this chapter shall be licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code.

(3) Ensure that every full service health care service plan provides for a physician and surgeon who is available on an on-call basis at all times the service is advertised to be available to enrollees and subscribers.

(4) Ensure that staff members handling enrollee or subscriber calls, who are not licensed, certified, or registered as required by paragraph (2), do not provide telephone medical advice. Those staff members may ask questions on behalf of a staff member who is licensed, certified, or registered as required by paragraph (2), in order to help ascertain the condition of an enrollee or subscriber so that the enrollee or subscriber can be referred to licensed staff. However, under no circumstances shall those staff members use the answers to those questions in an attempt to assess, evaluate, advise, or make any decision regarding the condition of an enrollee or subscriber or determine when an enrollee or subscriber needs to be seen by a licensed medical professional.

(5) Ensure that no staff member uses a title or designation when speaking to an enrollee or subscriber that may cause a reasonable person to believe that the staff member is a licensed, certified, or registered professional described in Section 4999.2 of the Business and Professions Code unless the staff member is a licensed, certified, or registered professional.

(6) Ensure that the in-state or out-of-state telephone medical advice service designates an agent for service of process in California and files this designation with the director.

(7) Require that the in-state or out-of-state telephone medical advice service makes and maintains records for a period of five years after the telephone medical advice services are provided, including, but not limited to, oral or written transcripts of all medical advice conversations with the health care service plan's enrollees or subscribers in California and copies of all complaints. If the records of telephone medical advice services are kept out of state, the health care service plan shall, upon the request of the director, provide the records to the director within 10 days of the request.

(8) Ensure that the telephone medical advice services are provided consistent with good professional practice.

(b) The director shall forward to the Department of Consumer Affairs, within 30 days of the end of each calendar quarter, data regarding complaints filed with the department concerning telephone medical advice services.

(c) For purposes of this section, "telephone medical advice" means a telephonic communication between a patient and a health care professional in which the health care professional's primary function is to provide to the patient a telephonic response to the patient's questions regarding his or her or a family member's medical care or treatment. "Telephone medical advice" includes assessment, evaluation, or advice provided to patients or their family members.

SEC. 43. Section 10279 of the Insurance Code is amended to read:

10279. (a) Every disability insurer that provides group or individual policies of disability, or both, that provides, operates, or contracts for, telephone medical advice services to its insureds shall do all of the following:

(1) Ensure that the in-state or out-of-state telephone medical advice service complies with the requirements of Chapter 15 (commencing with Section 4999) of Division 2 of the Business and Professions Code.

(2) Ensure that the staff providing telephone medical advice services for the in-state or out-of-state telephone medical advice service hold a valid California license as a registered nurse or a valid license in the state within which they provide telephone medical advice services as a physician and surgeon or physician assistant and are operating consistent with the laws governing their respective scopes of practice.

(3) Ensure that a physician and surgeon is available on an on-call basis at all times the service is advertised to be available to enrollees and subscribers.

(4) Ensure that the in-state or out-of-state telephone medical advice service designates an agent for service of process in California and files this designation with the commissioner.

(5) Require that the in-state or out-of-state telephone medical advice service makes and maintains records for a period of five years after the telephone medical advice services are provided, including, but not limited to, oral or written transcripts of all medical advice conversations with the disability insurer's insureds in California and copies of all complaints. If

the records of telephone medical advice services are kept out of state, the insurer shall, upon the request of the director, provide the records to the director within 10 days of the request.

(6) Ensure that the telephone medical advice services are provided consistent with good professional practice.

(b) The commissioner shall forward to the Department of Consumer Affairs, within 30 days of the end of each calendar quarter, data regarding complaints filed with the department concerning telephone medical advice services.

SEC. 44. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 2

Assembly Bill No. 1069

CHAPTER 316

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

[Approved by Governor September 13, 2016. Filed with Secretary of State September 13, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including a pharmacy that is owned by, or contracts with, the county, may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards, and that includes lot numbers and expiration dates, is eligible for donation to the program. Existing law prohibits medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity. Existing law requires medication donated to the repository and distribution program to be maintained in the donated packaging units.

This bill would authorize a pharmacy that exists solely to operate the repository and distribution program to repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The bill would require a pharmacy that repackages medication to have repackaging policies and procedures in place for identifying and recalling medications, and to label the repackaged medicine with the earliest expiration date.

The people of the State of California do enact as follows:

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in Section 150201, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication

donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the

pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

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

(i) (1) Except as provided in paragraph (2), medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(2) A pharmacy that exists solely to operate the repository and distribution program may repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date.

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

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

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Assembly Bill No. 1114

CHAPTER 602

An act to add Section 14132.968 to the Welfare and Institutions Code, relating to health care, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 25, 2016. Filed with Secretary of State September 25, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1114, Eggman. Medi-Cal: pharmacist services.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law provides for a schedule of benefits covered by the Medi-Cal program, including the purchase of prescribed drugs subject to the Medi-Cal list of contract drugs and utilization controls. Existing law requires a pharmacy provider under the Medi-Cal program to submit his or her usual and customary charge, as defined, when billing the Medi-Cal program for prescribed drugs. The Pharmacy Law specifies the functions a pharmacist is authorized to perform, including furnishing nicotine replacement products and administering immunizations, as specified.

This bill would add to the schedule of benefits pharmacist services, as specified, subject to department protocols and utilization controls. The bill would require the rate of reimbursement for pharmacist services to be at 85% of the fee schedule for physician services under the Medi-Cal program and would require the department to establish a fee schedule. The bill would authorize the department to implement these provisions by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action, until regulations are adopted, and would require the department to adopt those regulations by July 1, 2021. Commencing July 1, 2017, the bill would require the department to provide a status report to the Legislature on a semiannual basis until regulations have been adopted. The bill would require these provisions to be implemented only to the extent that federal financial participation is available and the necessary federal approvals are obtained.

This bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 14132.968 is added to the Welfare and Institutions Code, immediately following Section 14132.966, to read:

14132.968. (a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel medications as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone hydrochloride as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering immunizations as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement therapy as authorized in Section 4052.9 of the Business and Professions Code.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section does not restrict or prohibit any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Commencing July 1, 2017, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to make pharmacist services available as a benefit under the Medi-Cal program at the earliest possible time, it is necessary that this act take effect immediately.

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Assembly Bill No. 1386

CHAPTER 374

An act to add Section 4119.4 to the Business and Professions Code, to amend Section 1714.23 of the Civil Code, to amend Section 49414 of the Education Code, and to amend Section 1797.197a of the Health and Safety Code, relating to emergency medical care.

[Approved by Governor September 16, 2016. Filed with Secretary of State September 16, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1386, Low. Emergency medical care: epinephrine auto-injectors.

(1) Existing law authorizes a prehospital emergency medical care person, first responder, or lay rescuer to use an epinephrine auto-injector to render emergency care to another person, as specified. Existing law requires the Emergency Medical Services Authority to approve authorized training providers and the minimum standards for training and the use and administration of epinephrine auto-injectors. The existing Pharmacy Law also authorizes a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care person, first responder, or lay rescuer for the purpose of rendering emergency care in accordance with these provisions. A violation of the Pharmacy Law is a crime. Existing law requires school districts, county offices of education, and charter schools to provide emergency epinephrine auto-injectors, as defined, to school nurses and trained personnel who have volunteered to use epinephrine auto-injectors under emergency circumstances, as specified, and authorizes school nurses and trained personnel to use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

This bill would permit an "authorized entity," as defined, to use an epinephrine auto-injector to render emergency care to another person in accordance with these provisions. The bill would also authorize a pharmacy to furnish epinephrine auto-injectors to an authorized entity, as provided. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program. The bill would require an authorized entity to create and maintain a specified operations plan relating to its use of epinephrine auto-injectors, and would require those entities to submit a report to the Emergency Medical Services Authority of each incident that involves the administration of an epinephrine auto-injector, not more than 30 days after each use. The bill would also require the authority to publish an annual report summarizing the reports submitted to the authority pursuant to the bill's provisions. The bill would define the term "epinephrine

auto-injector" for purposes of these provisions and other related provisions that authorize the use of epinephrine auto-injectors, as specified.

(2) Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself. Existing law also provides that a prehospital emergency care person, first responder, or lay rescuer who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards.

This bill would provide that an authorized entity is not liable for any civil damages resulting from any act or omission connected to the administration of an epinephrine auto-injector, as specified. The bill would also exempt an authorizing physician and surgeon from certain sanctions for the issuance of an epinephrine auto-injector under those provisions, except as specified.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4119.4 is added to the Business and Professions Code, to read:

4119.4. (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.

SEC. 2. Section 1714.23 of the Civil Code is amended to read:

1714.23. (a) For purposes of this section, the following definitions shall apply:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "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.

(b) (1) Any person described in subdivision (b) of Section 1797.197a of the Health and Safety Code who administers an epinephrine auto-injector, in good faith and not for compensation, to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with the requirements and standards of Section 1797.197a of the Health and Safety Code.

(2) (A) An authorized entity shall not be liable for any civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct connected to the administration of an epinephrine auto-injector by any one of its employees, volunteers, or agents who is a lay rescuer, as defined by paragraph (4) of subdivision (a) of Section 1797.197a of the Health and Safety Code, if the entity has complied with all applicable requirements of Section 1797.197a of the Health and Safety Code.

(B) The failure of an authorized entity to possess or administer an epinephrine auto-injector shall not result in civil liability.

(3) This subdivision does not affect any other immunity or defense that is available under law.

(c) The protection specified in paragraph (1) of subdivision (b) shall not apply in a case of personal injury or wrongful death that results from the gross negligence or willful or wanton misconduct of the person who renders emergency care treatment by the use of an epinephrine auto-injector.

(d) Nothing in this section relieves a manufacturer, designer, developer, distributor, or supplier of an epinephrine auto-injector of liability under any other applicable law.

(e) An authorizing physician and surgeon is not subject to professional review, liable in a civil action, or subject to criminal prosecution for the issuance of a prescription or order in accordance with Section 1797.197a of the Health and Safety Code unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

SEC. 3. Section 49414 of the Education Code is amended to read:

49414. (a) School districts, county offices of education, and charter schools shall provide emergency epinephrine auto-injectors to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

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

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, an insect sting, food allergy, drug reaction, and exercise.

(2) "Authorizing physician and surgeon" may include, but is not limited to, a physician and surgeon employed by, or contracting with, a local educational agency, a medical director of the local health department, or a local emergency medical services director.

(3) "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.

(4) "Qualified supervisor of health" may include, but is not limited to, a school nurse.

(5) "Volunteer" or "trained personnel" means an employee who has volunteered to administer epinephrine auto-injectors to a person if the person is suffering, or reasonably believed to be suffering, from anaphylaxis, has been designated by a school, and has received training pursuant to subdivision (d).

(c) Each private elementary and secondary school in the state may voluntarily determine whether or not to make emergency epinephrine

auto-injectors and trained personnel available at its school. In making this determination, a school shall evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to epinephrine auto-injectors and trained personnel. A private elementary or secondary school choosing to exercise the authority provided under this subdivision shall not receive state funds specifically for purposes of this subdivision.

(d) Each public and private elementary and secondary school in the state may designate one or more volunteers to receive initial and annual refresher training, based on the standards developed pursuant to subdivision (e), regarding the storage and emergency use of an epinephrine auto-injector from the school nurse or other qualified person designated by an authorizing physician and surgeon.

(e) (1) Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of epinephrine auto-injectors that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering epinephrine auto-injectors and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the American Academy of Allergy, Asthma and Immunology, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, Food Allergy Research and Education, the California Society of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, the Sean N. Parker Center for Allergy Research, and others.

(2) Training established pursuant to this subdivision shall include all of the following:

(A) Techniques for recognizing symptoms of anaphylaxis.

(B) Standards and procedures for the storage, restocking, and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including calling the emergency 911 telephone number and contacting, if possible, the pupil's parent and physician.

(D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.

(E) Instruction on how to determine whether to use an adult epinephrine auto-injector or a junior epinephrine auto-injector, which shall include consideration of a pupil's grade level or age as a guideline of equivalency for the appropriate pupil weight determination.

(F) Written materials covering the information required under this subdivision.

(3) Training established pursuant to this subdivision shall be consistent with the most recent Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs published by the federal

Centers for Disease Control and Prevention and the most recent guidelines for medication administration issued by the department.

(4) A school shall retain for reference the written materials prepared under subparagraph (F) of paragraph (2).

(f) A school district, county office of education, or charter school shall distribute a notice at least once per school year to all staff that contains the following information:

(1) A description of the volunteer request stating that the request is for volunteers to be trained to administer an epinephrine auto-injector to a person if the person is suffering, or reasonably believed to be suffering, from anaphylaxis, as specified in subdivision (b).

(2) A description of the training that the volunteer will receive pursuant to subdivision (d).

(g) (1) A qualified supervisor of health at a school district, county office of education, or charter school shall obtain from an authorizing physician and surgeon a prescription for each school for epinephrine auto-injectors that, at a minimum, includes, for elementary schools, one regular epinephrine auto-injector and one junior epinephrine auto-injector, and for junior high schools, middle schools, and high schools, if there are no pupils who require a junior epinephrine auto-injector, one regular epinephrine auto-injector. A qualified supervisor of health at a school district, county office of education, or charter school shall be responsible for stocking the epinephrine auto-injector and restocking it if it is used.

(2) If a school district, county office of education, or charter school does not have a qualified supervisor of health, an administrator at the school district, county office of education, or charter school shall carry out the duties specified in paragraph (1).

(3) A prescription pursuant to this subdivision may be filled by local or mail order pharmacies or epinephrine auto-injector manufacturers.

(4) An authorizing physician and surgeon shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

(h) A school nurse or, if the school does not have a school nurse or the school nurse is not onsite or available, a volunteer may administer an epinephrine auto-injector to a person exhibiting potentially life-threatening symptoms of anaphylaxis at school or a school activity when a physician is not immediately available. If the epinephrine auto-injector is used it shall be restocked as soon as reasonably possible, but no later than two weeks after it is used. Epinephrine auto-injectors shall be restocked before their expiration date.

(i) A volunteer shall initiate emergency medical services or other appropriate medical followup in accordance with the training materials retained pursuant to paragraph (4) of subdivision (e).

(j) A school district, county office of education, or charter school shall ensure that each employee who volunteers under this section will be provided

defense and indemnification by the school district, county office of education, or charter school for any and all civil liability, in accordance with, but not limited to, that provided in Division 3.6 (commencing with Section 810) of Title 1 of the Government Code. This information shall be reduced to writing, provided to the volunteer, and retained in the volunteer's personnel file.

(k) A state agency, the department, or a public school may accept gifts, grants, and donations from any source for the support of the public school carrying out the provisions of this section, including, but not limited to, the acceptance of epinephrine auto-injectors from a manufacturer or wholesaler.

SEC. 4. Section 1797.197a of the Health and Safety Code is amended to read:

1797.197a. (a) For purposes of this section, the following definitions shall apply:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Authorized entity" means any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course as described in subdivision (c).

(3) "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.

(4) "Lay rescuer" means any person who has met the training standards and other requirements of this section but who is not otherwise licensed or certified to use an epinephrine auto-injector on another person.

(5) "Prehospital emergency medical care person" has the same meaning as defined in paragraph (2) of subdivision (a) of Section 1797.189.

(b) A prehospital emergency medical care person or lay rescuer may use an epinephrine auto-injector to render emergency care to another person if all of the following requirements are met:

(1) The epinephrine auto-injector is legally obtained by prescription from an authorized health care provider or from an authorized entity that acquired the epinephrine auto-injector pursuant to subdivision (e).

(2) The epinephrine auto-injector is used on another, with the expressed or implied consent of that person, to treat anaphylaxis.

(3) The epinephrine auto-injector is stored and maintained as directed by the manufacturer's instructions for that product.

(4) The person using the epinephrine auto-injector has successfully completed a course of training with an authorized training provider, as

described in subdivision (c), and has current certification of training issued by the provider.

(5) The epinephrine auto-injectors obtained by prehospital emergency medical care personnel pursuant to Section 4119.3 of the Business and Professions Code shall be used only when functioning outside the course of the person's occupational duties, or as a volunteer, pursuant to this section.

(6) The Emergency Medical Services System is activated as soon as practicable when an epinephrine auto-injector is used.

(c) (1) The authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors pursuant to this section shall be established and approved, by the authority. The authority may designate existing training standards for the use and administration of epinephrine auto-injectors by prehospital emergency medical care personnel to satisfy the requirements of this section.

(2) The minimum training and requirements shall include all of the following components:

(A) Techniques for recognizing circumstances, signs, and symptoms of anaphylaxis.

(B) Standards and procedures for proper storage and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including activation of the Emergency Medical Services System, by calling the emergency 9-1-1 telephone number or otherwise alerting and summoning more advanced medical personnel and services.

(D) Compliance with all regulations governing the training, indications, use, and precautions concerning epinephrine auto-injectors.

(E) Written material covering the information required under this provision, including the manufacturer product information sheets on commonly available models of epinephrine auto-injectors.

(F) Completion of a training course in cardiopulmonary resuscitation and the use of an automatic external defibrillator (AED) for infants, children, and adults that complies with regulations adopted by the authority and the standards of the American Heart Association or the American Red Cross, and a current certification for that training.

(3) Training certification shall be valid for no more than two years, after which recertification with an authorized training provider is required.

(4) The director may, in accordance with regulations adopted by the authority, deny, suspend, or revoke any approval issued under this subdivision or may place any approved training provider on probation upon a finding by the director of an imminent threat to public health and safety, as evidenced by any of the following:

(A) Fraud.

(B) Incompetence.

(C) The commission of any fraudulent, dishonest, or corrupt act that is substantially related to the qualifications, functions, or duties of training program directors or instructors.

(D) Conviction of any crime that is substantially related to the qualifications, functions, or duties of training program directors or instructors. The record of conviction or a certified copy of the record shall be conclusive evidence of the conviction.

(E) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this section or the regulations promulgated by the authority pertaining to the review and approval of training programs in anaphylaxis and the use and administration of epinephrine auto-injectors, as described in this subdivision.

(d) (1) The authority shall assess a fee pursuant to regulation sufficient to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification under subdivision (c).

(2) The fees shall be deposited in the Specialized First Aid Training Program Approval Fund, which is hereby created in the State Treasury. All moneys deposited in the fund shall be made available, upon appropriation, to the authority for purposes described in paragraph (1).

(3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training Program Approval Fund, together with the interest earned, when requested by the authority.

(4) The authority shall maintain a reserve balance in the Specialized First Aid Training Program Approval Fund of 5 percent of annual revenues. Any increase in the fees deposited in the Specialized First Aid Training Program Approval Fund shall be effective upon determination by the authority that additional moneys are required to fund expenditures pursuant to subdivision (c).

(e) (1) An authorized health care provider may issue a prescription for an epinephrine auto-injector to a prehospital emergency medical care person or a lay rescuer for the purpose of rendering emergency care to another person upon presentation of a current epinephrine auto-injector certification card issued by the authority demonstrating that the person is trained and qualified to administer an epinephrine auto-injector pursuant to this section or any other law.

(2) An authorized health care provider may issue a prescription for an epinephrine auto-injector to an authorized entity if the authorized entity submits evidence it employs at least one person, or utilizes at least one volunteer or agent, who is trained and has a current epinephrine auto-injector certification card issued by the authority demonstrating that the person is qualified to administer an epinephrine auto-injector pursuant to this section.

(f) An authorized entity that possesses and makes available epinephrine auto-injectors shall do both of the following:

(1) Create and maintain on its premises an operations plan that includes all of the following:

(A) The name and contact number for the authorized health care provider who prescribed the epinephrine auto-injector.

(B) Where and how the epinephrine auto-injector will be stored.

(C) The names of the designated employees or agents who have completed the training program required by this section and who are authorized to administer the epinephrine auto-injector.

(D) How and when the epinephrine auto-injector will be inspected for an expiration date.

(E) The process to replace the expired epinephrine auto-injector, including the proper disposal of the expired epinephrine auto-injector or used epinephrine auto-injector in a sharps container.

(2) Submit to the authority, in a manner identified by the authority, a report of each incident that involves the use of an epinephrine auto-injector, not more than 30 days after each use. The authority shall annually publish a report that summarizes all reports submitted to it under this subdivision.

(g) This section shall not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical aid pursuant to Section 49414 of the Education Code.

(h) This section shall not be construed to limit or restrict the ability of prehospital emergency medical care personnel, under any other statute or regulation, to administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification beyond what is already required under the other statute or regulation.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Assembly Bill No. 1748

CHAPTER 557

An act to add Section 4119.8 to the Business and Professions Code, and to add Section 49414.3 to the Education Code, relating to pupils.

[Approved by Governor September 24, 2016. Filed with Secretary of State September 24, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1748, Mayes. Pupils: pupil health: opioid antagonist.

(1) Existing law authorizes a pharmacy to furnish epinephrine auto-injectors to a school district, county office of education, or charter school if certain conditions are met. Existing law requires the school district, county office of education, or charter school to maintain records regarding the acquisition and disposition of epinephrine auto-injectors furnished by the pharmacy for a period of 3 years from the date the records were created.

This bill would authorize a pharmacy to furnish naloxone hydrochloride or another opioid antagonist to a school district, county office of education, or charter school if certain conditions are met. The bill would require the school district, county office of education, or charter school to maintain records regarding the acquisition and disposition of naloxone hydrochloride or another opioid antagonist furnished by the pharmacy for a period of 3 years from the date the records were created.

(2) Under existing law, the governing board of a school district is required to give diligent care to the health and physical development of pupils and may employ properly certified persons for that work. Existing law requires school districts, county offices of education, and charter schools to provide emergency epinephrine auto-injectors to school nurses or trained volunteer personnel and authorizes school nurses and trained personnel to use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction, as provided.

This bill would authorize a school district, county office of education, or charter school to provide emergency naloxone hydrochloride or another opioid antagonist to school nurses and trained personnel who have volunteered, as specified, and authorizes school nurses and trained personnel to use naloxone hydrochloride or another opioid antagonist to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose. The bill would expressly authorize each public and private elementary and secondary school in the state to voluntarily determine whether or not to make emergency naloxone hydrochloride or another opioid antagonist and trained personnel available at its school and to designate one or more school personnel to receive prescribed training

regarding naloxone hydrochloride or another opioid antagonist from individuals in specified positions.

The bill would require the Superintendent of Public Instruction to establish minimum standards of training for the administration of naloxone hydrochloride or another opioid antagonist, to review these standards every 5 years or sooner as specified, and to consult with organizations and providers with expertise in administering naloxone hydrochloride or another opioid antagonist and administering medication in a school environment in developing and reviewing those standards. The bill would require the State Department of Education to include on its Internet Web site a clearinghouse for best practices in training nonmedical personnel to administer naloxone hydrochloride or another opioid antagonist to pupils.

The bill would require a school district, county office of education, or charter school choosing to exercise the authority to provide emergency naloxone hydrochloride or another opioid antagonist to provide the training for the volunteers at no cost to the volunteers and during the volunteers' regular working hours. The bill would require a qualified supervisor of health or administrator at a school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency medical aid to obtain the prescription for naloxone hydrochloride or another opioid antagonist from an authorizing physician and surgeon, as defined, and would authorize the prescription to be filled by local or mail order pharmacies or naloxone hydrochloride or another opioid antagonist manufacturers.

The bill would authorize school nurses or, if the school does not have a school nurse, a person who has received training regarding naloxone hydrochloride or another opioid antagonist to immediately administer naloxone hydrochloride or another opioid antagonist under certain circumstances. The bill would provide that volunteers may administer naloxone hydrochloride or another opioid antagonist only by nasal spray or by auto-injector, as specified.

The bill would prohibit an authorizing physician and surgeon from being subject to professional review, being liable in a civil action, or being subject to criminal prosecution for any act in the issuing of a prescription or order, pursuant to these provisions, unless the act constitutes gross negligence or willful or malicious conduct. The bill would prohibit a person trained under these provisions who administers naloxone hydrochloride or another opioid antagonist, in good faith and not for compensation, to a person who appears to be experiencing an opioid overdose from being subject to professional review, being liable in a civil action, or being subject to criminal prosecution for this administration.

The people of the State of California do enact as follows:

SECTION 1. Section 4119.8 is added to the Business and Professions Code, to read:

4119.8. (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.

SEC. 2. Section 49414.3 is added to the Education Code, to read:

49414.3. (a) School districts, county offices of education, and charter schools may provide emergency naloxone hydrochloride or another opioid antagonist to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use naloxone hydrochloride or another opioid antagonist to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose.

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

(1) "Authorizing physician and surgeon" may include, but is not limited to, a physician and surgeon employed by, or contracting with, a local educational agency, a medical director of the local health department, or a local emergency medical services director.

(2) "Auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of an opioid antagonist into the human body and approved by the federal Food and Drug Administration for layperson use.

(3) "Opioid antagonist" means naloxone hydrochloride or another drug approved by the federal Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body, and has been approved for the treatment of an opioid overdose.

(4) "Qualified supervisor of health" may include, but is not limited to, a school nurse.

(5) "Volunteer" or "trained personnel" means an employee who has volunteered to administer naloxone hydrochloride or another opioid antagonist to a person if the person is suffering, or reasonably believed to

be suffering, from an opioid overdose, has been designated by a school, and has received training pursuant to subdivision (d).

(c) Each public and private elementary and secondary school in the state may voluntarily determine whether or not to make emergency naloxone hydrochloride or another opioid antagonist and trained personnel available at its school. In making this determination, a school shall evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to naloxone hydrochloride or another opioid antagonist and trained personnel. A private elementary or secondary school choosing to exercise the authority provided under this subdivision shall not receive state funds specifically for purposes of this subdivision.

(d) (1) Each public and private elementary and secondary school in the state may designate one or more volunteers to receive initial and annual refresher training, based on the standards developed pursuant to subdivision (e), regarding the storage and emergency use of naloxone hydrochloride or another opioid antagonist from the school nurse or other qualified person designated by an authorizing physician and surgeon. A benefit shall not be granted to or withheld from any individual based on his or her offer to volunteer, and there shall be no retaliation against any individual for rescinding his or her offer to volunteer, including after receiving training. Any school district, county office of education, or charter school choosing to exercise the authority provided under this subdivision shall provide the training for the volunteers at no cost to the volunteer and during the volunteer's regular working hours.

(2) An employee who volunteers pursuant to this section may rescind his or her offer to administer emergency naloxone hydrochloride or another opioid antagonist at any time, including after receipt of training.

(e) (1) The Superintendent shall establish minimum standards of training for the administration of naloxone hydrochloride or another opioid antagonist that satisfies the requirements of paragraph (2). Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of naloxone hydrochloride or other opioid antagonists that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering naloxone hydrochloride or another opioid antagonist and administering medication in a school environment, including, but not limited to, the California Society of Addiction Medicine, the Emergency Medical Services Authority, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, and others.

(2) Training established pursuant to this subdivision shall include all of the following:

(A) Techniques for recognizing symptoms of an opioid overdose.

(B) Standards and procedures for the storage, restocking, and emergency use of naloxone hydrochloride or another opioid antagonist.

(C) Basic emergency followup procedures, including, but not limited to, a requirement for the school or charter school administrator or, if the administrator is not available, another school staff member to call the emergency 911 telephone number and to contact the pupil's parent or guardian.

(D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.

(E) Written materials covering the information required under this subdivision.

(3) Training established pursuant to this subdivision shall be consistent with the most recent guidelines for medication administration issued by the department.

(4) A school shall retain for reference the written materials prepared under subparagraph (E) of paragraph (2).

(5) The department shall include on its Internet Web site a clearinghouse for best practices in training nonmedical personnel to administer naloxone hydrochloride or another opioid antagonist to pupils.

(f) Any school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency aid shall distribute a notice at least once per school year to all staff that contains the following information:

(1) A description of the volunteer request stating that the request is for volunteers to be trained to administer naloxone hydrochloride or another opioid antagonist to a person if the person is suffering, or reasonably believed to be suffering, from an opioid overdose.

(2) A description of the training that the volunteer will receive pursuant to subdivision (d).

(3) The right of an employee to rescind his or her offer to volunteer pursuant to this section.

(4) A statement that no benefit will be granted to or withheld from any individual based on his or her offer to volunteer and that there will be no retaliation against any individual for rescinding his or her offer to volunteer, including after receiving training.

(g) (1) A qualified supervisor of health at a school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency aid shall obtain from an authorizing physician and surgeon a prescription for each school for naloxone hydrochloride or another opioid antagonist. A qualified supervisor of health at a school district, county office of education, or charter school shall be responsible for stocking the naloxone hydrochloride or another opioid antagonist and restocking it if it is used.

(2) If a school district, county office of education, or charter school does not have a qualified supervisor of health, an administrator at the school district, county office of education, or charter school shall carry out the duties specified in paragraph (1).

(3) A prescription pursuant to this subdivision may be filled by local or mail order pharmacies or naloxone hydrochloride or another opioid antagonist manufacturers.

(4) An authorizing physician and surgeon shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

(h) (1) A school nurse or, if the school does not have a school nurse or the school nurse is not onsite or available, a volunteer may administer naloxone hydrochloride or another opioid antagonist to a person exhibiting potentially life-threatening symptoms of an opioid overdose at school or a school activity when a physician is not immediately available. If the naloxone hydrochloride or another opioid antagonist is used it shall be restocked as soon as reasonably possible, but no later than two weeks after it is used. Naloxone hydrochloride or another opioid antagonist shall be restocked before its expiration date.

(2) Volunteers may administer naloxone hydrochloride or another opioid antagonist only by nasal spray or by auto-injector.

(3) A volunteer shall be allowed to administer naloxone hydrochloride or another opioid antagonist in a form listed in paragraph (2) that the volunteer is most comfortable with.

(i) A school district, county office of education, or charter school electing to utilize naloxone hydrochloride or another opioid antagonist for emergency aid shall ensure that each employee who volunteers under this section will be provided defense and indemnification by the school district, county office of education, or charter school for any and all civil liability, in accordance with, but not limited to, that provided in Division 3.6 (commencing with Section 810) of Title 1 of the Government Code. This information shall be reduced to writing, provided to the volunteer, and retained in the volunteer's personnel file.

(j) (1) Notwithstanding any other law, a person trained as required under subdivision (d), who administers naloxone hydrochloride or another opioid antagonist, in good faith and not for compensation, to a person who appears to be experiencing an opioid overdose shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for his or her acts or omissions in administering the naloxone hydrochloride or another opioid antagonist.

(2) The protection specified in paragraph (1) shall not apply in a case of gross negligence or willful and wanton misconduct of the person who renders emergency care treatment by the use of naloxone hydrochloride or another opioid antagonist.

(3) Any public employee who volunteers to administer naloxone hydrochloride or another opioid antagonist pursuant to subdivision (d) is not providing emergency medical care "for compensation," notwithstanding the fact that he or she is a paid public employee.

(k) A state agency, the department, or a public school may accept gifts, grants, and donations from any source for the support of the public school carrying out the provisions of this section, including, but not limited to, the acceptance of naloxone hydrochloride or another opioid antagonist from a manufacturer or wholesaler.

O

Senate Bill No. 482

CHAPTER 708

An act to amend Sections 11165 and 11165.1 of, and to add Section 11165.4 to, the Health and Safety Code, relating to controlled substances.

[Approved by Governor September 27, 2016. Filed with Secretary of State September 27, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 482, Lara. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, administer, furnish, or dispense these controlled substances. Existing law requires dispensing pharmacies and clinics to report specified information for each prescription of a Schedule II, Schedule III, or Schedule IV controlled substance to the department.

This bill would require a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance to consult the CURES database to review a patient's controlled substance history no earlier than 24 hours, or the previous business day, before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every 4 months thereafter if the substance remains part of the treatment of the patient. The bill would exempt a veterinarian and a pharmacist from this requirement. The bill would also exempt a health care practitioner from this requirement under specified circumstances, including, among others, if prescribing, ordering, administering, or furnishing a controlled substance to a patient receiving hospice care, to a patient admitted to a specified facility for use while on facility premises, or to a patient as part of a treatment for a surgical procedure in a specified facility if the quantity of the controlled substance does not exceed a nonrefillable 5-day supply of the controlled substance that is to be used in accordance with the directions for use. The bill would require, if a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient pursuant to one of those exemptions, the health care practitioner to consult the CURES database before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every 4 months thereafter if the substance remains part of the treatment of the patient.

This bill would provide that a health care practitioner who fails to consult the CURES database is required to be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board. The bill would make the above-mentioned provisions operative 6 months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, user support, and education, as specified.

This bill would also exempt a health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, from civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

Existing law requires the operation of the CURES database to comply with all applicable federal and state privacy and security laws and regulations. Existing law authorizes the disclosure of data obtained from the CURES database to agencies and entities only for specified purposes and requires the Department of Justice to establish policies, procedures, and regulations regarding the use, access, disclosure, and security of the information within the CURES database.

This bill would authorize a health care practitioner to provide a patient with a copy of the patient's CURES patient activity report if no additional CURES data is provided. The bill would also prohibit a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances from obtaining data from the CURES database.

The people of the State of California do enact as follows:

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department

shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

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

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

SEC. 2. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled

substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

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

(i) Materially falsifying an application for a subscriber.

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

(iii) Suspended or revoked federal DEA registration.

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

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

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

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

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

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

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

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising

from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

SEC. 3. Section 11165.4 is added to the Health and Safety Code, to read:

11165.4. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient, he or she shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before he or she prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason he or she did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within his or her control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription

in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) 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.

O

Senate Bill No. 952

CHAPTER 150

An act to amend Section 4202 of the Business and Professions Code, relating to healing arts.

[Approved by Governor August 19, 2016. Filed with Secretary of State August 19, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 952, Anderson. Pharmacy technicians: licensure requirements.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy technicians by the California State Board of Pharmacy. Existing law authorizes the California State Board of Pharmacy to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent and has obtained an associate's degree in pharmacy technology, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board.

This bill would substitute for the Pharmacy Technician Certification Board a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the California State Board of Pharmacy.

The people of the State of California do enact as follows:

SECTION 1. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board.

(4) Is certified by 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.

O

Senate Bill No. 999

CHAPTER 499

An act to amend Section 4064.5 of the Business and Professions Code, to amend Section 1367.25 of the Health and Safety Code, to amend Section 10123.196 of the Insurance Code, and to add Section 14000.01 to the Welfare and Institutions Code, relating to contraceptives.

[Approved by Governor September 23, 2016. Filed with Secretary of State September 23, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 999, Pavley. Health care coverage: contraceptives: annual supply.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law also provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services through, among other things, managed care plans licensed under the act that contract with the State Department of Health Care Services. Existing law requires a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, to provide coverage for women for all prescribed and FDA-approved female contraceptive drugs, devices, and products, as well as voluntary sterilization procedures, contraceptive education and counseling, and related followup services.

This bill would require a health care service plan or a health insurance policy issued, amended, renewed, or delivered on or after January 1, 2017, to cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed at one time for an enrollee or insured at one time by a provider, pharmacist, or at a location licensed or authorized to dispense drugs or supplies. The bill would specifically provide that a health care service plan contract or an insurance policy is not required to cover contraceptives provided by an out-of-network provider, pharmacy, or other location, except as authorized by state or federal law or by the plan or insurer's policies governing out-of-network coverage. The bill would also prohibit a health care service plan or health insurer, in the absence of clinical contraindications, from imposing utilization controls limiting the supply of FDA-approved, self-administered hormonal contraceptives that may be furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply. The bill would include Medi-Cal managed care

plans, as specified, in the definition of a health care service plan for purposes of these provisions, and would require the State Department of Health Care Services to seek federal approval, if necessary, and to issue all-plan letters or similar instructions to implement these provisions. Because a willful violation of the bill's requirements by a health care service plan would be a crime, the bill would impose a state-mandated local program.

Existing law authorizes a pharmacist to 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 the patient has met specified requirements, including having completed an initial 30-day supply of the drug. Existing law prohibits a pharmacist from dispensing a greater supply of a dangerous drug if the prescriber indicates "no change to quantity" on the prescription. Existing law authorizes a pharmacist to 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, as specified.

This bill would require a pharmacist to 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. The bill would authorize a pharmacist furnishing an FDA-approved, self-administered hormonal contraceptive, pursuant to the authorization described above, to furnish up to a 12-month supply at one time at the patient's request.

This bill would incorporate changes to Section 4064.5 of the Business and Professions Code proposed by both this bill and SB 253, which would become operative only if both bills are enacted and become effective on or before January 1, 2017, and this bill is chaptered last.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature hereby finds all of the following:

(1) California has a long history of, and commitment to, expanding access to services that aim to reduce the risk of unintended pregnancies and improving reproductive health outcomes.

(2) California's Family Planning, Access, Care, and Treatment (Family PACT) Waiver Program, created in 1999, is viewed nationally as the "gold standard" of publicly funded programs providing access to reproductive health care. The program has long recognized the value and importance of providing women with a year's supply of birth control.

(3) The Affordable Care Act (ACA) and subsequent federal regulations made contraceptive coverage a national policy by requiring most private health insurance plans to provide coverage for a broad range of preventive services without cost sharing, including FDA-approved prescription contraceptives.

(4) Since the passage of the ACA, many states have passed laws strengthening or expanding this federal contraceptive coverage requirement. In 2014, California passed the Contraceptive Coverage Equity Act of 2014, which requires plans to cover all prescribed FDA-approved contraceptives for women without cost sharing, and requires plans to cover at least one therapeutic equivalent of a prescribed contraceptive drug, device, or product.

(5) Numerous studies support what California has determined for decades in the Family PACT program: dispensing a 12-month supply of birth control at one time has numerous benefits, including, but not limited to, reducing a woman's odds of having an unintended pregnancy by 30 percent, increasing contraception continuation rates, and decreasing costs per client to insurers by reducing the number of pregnancy tests and pregnancies.

(6) Access to contraception is a key element in shaping women's health and well-being. Nearly all women have used contraceptives at some point in their lives, and 62 percent are currently using at least one method.

(7) Several states have mirrored the year-supply requirement for contraceptive coverage in their publicly funded family planning or Medicaid programs, recognizing the health benefits of reducing barriers to continuous and effective use of contraception. Recently, Oregon and Washington, D.C., have gone further to require private health care service plans and health insurance policies to also cover a 12-month supply of contraceptives. With California's history of leadership in establishing public policies that increase access to contraceptives, adopting a similar requirement is a natural progression of our state's commitment to reducing unintended pregnancy.

(b) It is therefore the intent of the Legislature to expand on California's existing contraceptive coverage policy by requiring all health care service plans and health insurance policies, including both commercial and Medi-Cal managed care plans, to cover a 12-month supply of a prescribed FDA-approved contraceptive, such as the ring, the patch, and oral contraceptives.

SEC. 2. Section 4064.5 of the Business and Professions Code is amended to read:

4064.5. (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.

SEC. 2.5. Section 4064.5 of the Business and Professions Code is amended to read:

4064.5. (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 does not apply to psychotropic medication or psychotropic drugs as described in Sections 369.5 and 739.5 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.

SEC. 3. Section 1367.25 of the Health and Safety Code is amended to read:

1367.25. (a) A group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2000, to December 31, 2015, inclusive, and an individual health care service plan contract that is amended, renewed, or delivered on or after January 1, 2000, to December 31, 2015, inclusive, except for a specialized health care service plan contract, shall provide coverage for the following, under general terms and conditions applicable to all benefits:

(1) A health care service plan contract that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods designated by the plan. In the event the patient's participating provider, acting within his or her scope of practice, determines that none of the methods designated by the plan is medically appropriate for the patient's medical or personal history, the plan shall also provide coverage for another FDA-approved, medically appropriate prescription contraceptive method prescribed by the patient's provider.

(2) Benefits for an enrollee under this subdivision shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(b) (1) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for women:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the enrollee's provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) Except for a grandfathered health plan, a health care service plan subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision. Cost sharing shall not be imposed on any Medi-Cal beneficiary.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a health care service plan is not

required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision.

(C) If a covered therapeutic equivalent of a drug, device, or product is not available, or is deemed medically inadvisable by the enrollee's provider, a health care service plan shall provide coverage, subject to a plan's utilization management procedures, for the prescribed contraceptive drug, device, or product without cost sharing. Any request by a contracting provider shall be responded to by the health care service plan in compliance with the Knox-Keene Health Care Service Plan Act of 1975, as set forth in this chapter and, as applicable, with the plan's Medi-Cal managed care contract.

(3) Except as otherwise authorized under this section, a health care service plan shall not impose any restrictions or delays on the coverage required under this subdivision.

(4) Benefits for an enrollee under this subdivision shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(5) For purposes of paragraphs (2) and (3) of this subdivision, and subdivision (d), "health care service plan" shall include Medi-Cal managed care plans that contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

(c) Notwithstanding any other provision of this section, a religious employer may request a health care service plan contract without coverage for FDA-approved contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a health care service plan contract shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization as described in Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this section shall provide written notice to prospective enrollees prior to enrollment with the plan, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(d) (1) Every health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed or furnished at one time for an enrollee by a provider, pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies.

(2) Nothing in this subdivision shall be construed to require a health care service plan contract to cover contraceptives provided by an out-of-network provider, pharmacy, or location licensed or otherwise authorized to dispense drugs or supplies, except as may be otherwise authorized by state or federal law or by the plan's policies governing out-of-network coverage.

(3) Nothing in this subdivision shall be construed to require a provider to prescribe, furnish, or dispense 12 months of self-administered hormonal contraceptives at one time.

(4) A health care service plan subject to this subdivision, in the absence of clinical contraindications, shall not impose utilization controls or other forms of medical management limiting the supply of FDA-approved, self-administered hormonal contraceptives that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply.

(e) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an enrollee.

(f) This section shall not be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for contraceptive drugs, devices, and products.

(g) This section shall not be construed to require an individual or group health care service plan contract to cover experimental or investigational treatments.

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

(1) "Grandfathered health plan" has the meaning set forth in Section 1251 of PPACA.

(2) "PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to health care service plan contracts issued, amended, or renewed on or after January 1, 2016, "provider" means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of this code.

SEC. 4. Section 10123.196 of the Insurance Code is amended to read:

10123.196. (a) An individual or group policy of disability insurance issued, amended, renewed, or delivered on or after January 1, 2000, through December 31, 2015, inclusive, that provides coverage for hospital, medical, or surgical expenses, shall provide coverage for the following, under the same terms and conditions as applicable to all benefits:

(1) A disability insurance policy that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods, as designated by the insurer. If an insured's health care provider determines that none of the methods designated by the disability insurer is medically appropriate for the insured's medical or personal history, the insurer shall, in the alternative, provide coverage for some other FDA-approved prescription contraceptive method prescribed by the patient's health care provider.

(2) Coverage with respect to an insured under this subdivision shall be identical for an insured's covered spouse and covered nonspouse dependents.

(b) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for women:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved, contraceptive drugs, devices, and other products for women, including all FDA-approved, contraceptive drugs, devices, and products available over the counter, as prescribed by the insured's provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) Except for a grandfathered health plan, a disability insurer subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a disability insurer is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision.

(C) If a covered therapeutic equivalent of a drug, device, or product is not available, or is deemed medically inadvisable by the insured's provider, a disability insurer shall provide coverage, subject to an insurer's utilization management procedures, for the prescribed contraceptive drug, device, or product without cost sharing. Any request by a contracting provider shall be responded to by the disability insurer in compliance with Section 10123.191.

(3) Except as otherwise authorized under this section, an insurer shall not impose any restrictions or delays on the coverage required under this subdivision.

(4) Coverage with respect to an insured under this subdivision shall be identical for an insured's covered spouse and covered nonspouse dependents.

(c) This section shall not be construed to deny or restrict in any way any existing right or benefit provided under law or by contract.

(d) This section shall not be construed to require an individual or group disability insurance policy to cover experimental or investigational treatments.

(e) Notwithstanding any other provision of this section, a religious employer may request a disability insurance policy without coverage for contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a disability insurance policy shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization pursuant to Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this section shall provide written notice to any prospective employee once an offer of employment has been made, and prior to that person commencing that employment, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(f) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed or furnished at one time for an insured by a provider, pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies.

(2) Nothing in this subdivision shall be construed to require a policy to cover contraceptives provided by an out-of-network provider, pharmacy, or location licensed or otherwise authorized to dispense drugs or supplies, except as may be otherwise authorized by state or federal law or by the insurer's policies governing out-of-network coverage.

(3) Nothing in this subdivision shall be construed to require a provider to prescribe, furnish, or dispense 12 months of self-administered hormonal contraceptives at one time.

(4) A health insurer subject to this subdivision, in the absence of clinical contraindications, shall not impose utilization controls or other forms of medical management limiting the supply of FDA-approved, self-administered hormonal contraceptives that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply.

(g) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her

scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an insured.

(h) This section only applies to disability insurance policies or contracts that are defined as health benefit plans pursuant to subdivision (a) of Section 10198.6, except that for accident only, specified disease, or hospital indemnity coverage, coverage for benefits under this section applies to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. This section shall not be construed as imposing a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

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

(1) "Grandfathered health plan" has the meaning set forth in Section 1251 of PPACA.

(2) "PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to policies of disability insurance issued, amended, or renewed on or after January 1, 2016, "health care provider" means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

SEC. 5. Section 14000.01 is added to the Welfare and Institutions Code, to read:

14000.01. The department shall seek federal approval, if necessary, and shall issue all-plan letters or similar instructions to implement subdivision (d) of Section 1367.25 of the Health and Safety Code.

SEC. 6. Section 2.5 of this bill incorporates amendments to Section 4064.5 of the Business and Professions Code proposed by both this bill and Senate Bill 253. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2017, (2) each bill amends Section 4064.5 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 253, in which case Section 2 of this bill shall not become operative.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Senate Bill No. 1229

CHAPTER 238

An act to add Section 1714.24 to the Civil Code, relating to pharmaceutical waste.

[Approved by Governor August 29, 2016. Filed with Secretary of State August 29, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1229, Jackson. Home-generated pharmaceutical waste: secure drug take-back bins.

Under existing law, the Medical Waste Management Act, the State Department of Public Health regulates the management and handling of medical waste, including pharmaceutical waste, as defined. The act generally prohibits a person from transporting, storing, treating, disposing, or causing the treatment of medical waste in a manner not authorized by the act. A violation of that provision is a crime.

Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter, has willfully or by want of ordinary care, brought the injury upon himself or herself.

This bill would provide that a collector, as defined, is not liable for civil damages, or subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back bin on its premises provided that the collector, not for compensation, acts in good faith to take specified steps, including that the collector regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of home-generated pharmaceutical waste, as defined, contained in the bins.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares the following:

(1) On October 12, 2010, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273; hereafter referred to as the Disposal Act) was enacted. Before the Disposal Act, individuals who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances had limited disposal options. The federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.; hereafter referred to as the CSA) only permitted individuals to destroy those substances themselves (e.g., by

flushing or discarding), surrender them to law enforcement, or seek assistance from the federal Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion. The Disposal Act amended the CSA to authorize specified individuals, referred to as "ultimate users," to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the United States Attorney General.

(2) On September 9, 2014, the DEA issued its final rule governing the secure disposal of controlled substances by registrants and ultimate users. Those regulations implement the Disposal Act by expanding the options available to collect controlled substances from ultimate users for the purpose of disposal, including take-back events, mail-back programs, and collection receptacle locations. Those regulations, among other things, allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles.

(b) It is the intent of the Legislature, with the enactment of this act, to do both of the following:

(1) Encourage the good faith participation of federally authorized entities to maintain secure drug take-back bins on their premises for the convenience and public health and safety of prescription drug consumers and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

(2) Limit the civil and criminal liability of participating entities that meet certain minimum standards and take reasonable care to ensure the health and safety of consumers and employees when maintaining secure drug take-back bins on their premises.

(c) The terms and conditions provided by subdivision (b) of Section 1714.24 of the Civil Code, as added by this act, shall be construed in a manner consistent with the requirements imposed by the DEA's final rule governing the secure disposal of controlled substances (79 Fed. Reg. 53519-70 (September 9, 2014)) and any regulations promulgated by the state.

SEC. 2. Section 1714.24 is added to the Civil Code, to read:

1714.24. (a) For purposes of this section, the following definitions shall apply:

(1) "Collector" includes only those entities authorized by and registered with the federal Drug Enforcement Administration to receive a controlled substance for the purpose of destruction, if the entity is in good standing with any applicable licensing authority.

(2) "Compensation" means reimbursement or funds received from a customer to compensate for the cost incurred in obtaining, installing, or maintaining a secure drug take-back bin. "Compensation" does not include reimbursement or funds received from any other person or entity, other than

a customer, to compensate for the costs incurred in obtaining, installing, or maintaining a secure drug take-back bin.

(3) "Home-generated pharmaceutical waste" means a pharmaceutical that is no longer wanted or needed by the consumer and includes any delivery system, such as pills, liquids, and inhalers.

(4) "Maintains" includes owning, leasing, operating, or otherwise hosting a secure drug take-back bin on the collector's premises.

(5) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Health and Safety Code and Section 321(g)(1) of Title 21 of the United States Code. "Pharmaceutical" includes controlled substances included in Schedule II, III, IV, or V of the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), but does not include a controlled substance included in Schedule I.

(6) "Secure drug take-back bin" means a collection receptacle as described in Section 1317.75 of Title 21 of the Code of Federal Regulations.

(b) Any collector that maintains a secure drug take-back bin shall not be liable in a civil action, or be subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back bin on its premises provided that the collector, not for compensation, acts in good faith to take all of the following steps to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the home-generated pharmaceutical waste contained in a secure drug take-back bin, unless the injury or harm results from the collector's gross negligence or willful and wanton misconduct:

(1) Complies with all applicable state and federal laws and regulations relating to the collection of home-generated pharmaceutical waste for disposal in secure drug take-back bins, including, but not limited to, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273).

(2) Notifies local law enforcement and any local environmental health department as to the existence and location of any secure drug take-back bin on the collector's premises and the status of the collector's registration as a collector with the federal Drug Enforcement Administration.

(3) Ensures that the secure drug take-back bin is placed in a location that is regularly monitored by employees of the registered collector.

(4) Ensures that conspicuous signage is posted on the secure drug take-back bin that clearly notifies customers as to what controlled and noncontrolled substances are and are not acceptable for deposit into the bin, as well as the hours during which collection is allowed.

(5) Ensures that public access to the secure drug take-back bin is limited to hours in which employees of the registered collector are present and able to monitor the operation of the secure drug take-back bin.

(6) Regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion. Record logs of those inspections shall be maintained and retained for two years, reflecting the date and time

of the inspection, and the initials of the employee inspecting the area. The logs shall be maintained in writing or electronically and may be combined with logs required by state or federal regulations. The logs may be used to demonstrate regular inspection of the area. Other records or reports mandated by federal or state regulations shall also be retained for a minimum of two years unless regulations mandate a longer period.

(7) Notifies local law enforcement authorities of any suspected or known tampering, theft, or significant loss of controlled substances, within one business day of discovery. If the collector maintains daily business hours, this notification shall be made within one calendar day.

(8) Notify local law enforcement as to any decision to discontinue its voluntary collection of controlled substances and provide documentation of its written notification to the federal Drug Enforcement Administration's Registration Unit as otherwise required under federal laws and regulations.

(c) Nothing in this section shall be construed to require entities that may qualify as a collector to acquire, maintain, or make available to the public a secure drug take-back bin on its premises.

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Attachment 3

Statutory Changes to Pharmacy Law

The below provisions take effect January 1, 2017 unless otherwise noted.

Business and Professions Code Changes

Section 4001 of the Business and Professions Code is amended to read:

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

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, ~~2017,~~ 2021, and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ repealed. Notwithstanding any other ~~provision of~~ law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

Section 4003 of the Business and Professions Code is amended to read:

(a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) This section shall remain in effect only until January 1, ~~2017,~~ 2021, and as of that date is ~~repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.~~ repealed.

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

(a) Any facility licensed by the board shall join the board's ~~e-mail~~ 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 ~~e-mail~~ email address with the board's ~~e-mail~~ email notification list within 30 days of a change in the facility's ~~e-mail~~ 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 ~~e-mail~~ email address to the board's ~~e-mail~~ email notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an ~~e-mail~~ 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 ~~e-mail~~ 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 ~~e-mail~~ email address with the board's ~~e-mail~~ email notification list within 30 days of any change in the owner's ~~e-mail~~ 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.

~~(d)~~ (5) This ~~section~~ subdivision shall become operative on July 1, ~~2010.~~ 2017.

Section 4034 is added to the Business and Professions Code, to read:

"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).

Section 4035 of the Business and Professions Code is amended to read:

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

Section 4081 of the Business and Professions Code is amended to read:

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

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

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

Section 4105.5 is added to the Business and Professions Code, to read:

(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).

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

(a) The board ~~may~~ 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 ~~injectable~~ drugs to a pharmacy pursuant to Section ~~4127.1.~~ 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.

Section 4110 of the Business and Professions Code is amended to read:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A

separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary ~~permit, when the ownership of a pharmacy is transferred from one person to another,~~ 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.~~

(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.

Section 4119.1 of the Business and Professions Code is amended to read:

(a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

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

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

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) ~~Nothing in this~~ 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.

Section 4119.4 is added to the Business and Professions Code, to read:

(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.

Section 4119.8 is added to the Business and Professions Code, to read:

(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.

Section 4126.9 is added to the Business and Professions Code, to read:

(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.

Section 4127 of the Business and Professions Code is amended to read:

(a) A pharmacy that compounds sterile drug products ~~for injection, administration into the eye, or inhalation~~ 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).

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

Section 4127.3 of the Business and Professions Code is amended to read:

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

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

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

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

Section 4127.7 of the Business and Professions Code is amended to read:

~~On and after July 1, 2005, a~~ A pharmacy shall compound sterile ~~injectable~~ products from one or more nonsterile ingredients in one of the following environments:

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

(b) An ISO class 5 cleanroom.

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

Section 4127.8 of the Business and Professions Code is amended to read:

The board may, at its discretion, issue a temporary license to compound ~~injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another,~~ 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.

Section 4127.9 of the Business and Professions Code is amended to read:

(a) A pharmacy licensed pursuant to Section 4127.1 or ~~4127.2, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that~~ 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.

Section 4128.6 of the Business and Professions Code is amended to read:

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

Article 7.7. Outsourcing Facilities

Section 4129 is added to the Business and Professions Code, to read

(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. is added to the Business and Professions Code, to read

(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. is added to the Business and Professions Code, to read:

(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. is added to the Business and Professions Code, to read:

(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. is added to the Business and Professions Code, to read:

(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. is added to the Business and Professions Code, to read:

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

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

(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.

Section 4161 of the Business and Professions Code is amended to read:

(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 ~~injectable~~ sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt

requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

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

Section 4180 of the Business and Professions Code is amended to read:

(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.

Section 4201 of the Business and Professions Code is amended to read:

(a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, ~~or~~ veterinary food-animal drug ~~retailer~~ 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.~~ 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, ~~or~~ veterinary food-animal drug ~~retailer~~ 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.

Section 4202 of the Business and Professions Code is amended to read:

(a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board.

(4) Is certified by ~~the Pharmacy Technician Certification Board.~~ *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.

Section 4203.5 is added to the Business and Professions Code, to read:

(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.

Section 4301 of the Business and Professions Code is amended to read:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been ~~procured by fraud or misrepresentation or~~ issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) ~~Gross immorality.~~ 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. ~~The record of the compromise is conclusive evidence of unprofessional conduct.~~

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this ~~chapter.~~ 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.

Section 4301.1 is added to the Business and Professions Code, to read:

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.

Section 4302 of the Business and Professions Code is amended to read:

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

Section 4303.1 is added to the Business and Professions Code, to read:

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.

Section 4307 of the Business and Professions Code is amended to read:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, ~~or partner~~ 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, ~~or partner~~ 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, ~~or partner~~ 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, ~~or partner,"~~ 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 ~~that~~ 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.

Section 4308 of the Business and Professions Code is amended to read:

Whenever a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, ~~or partner~~ partner, or in any other position with 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, ~~or partner~~ 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.

Section 4312 of the Business and Professions Code is amended to read:

(a) The board may cancel the license of a wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ 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, ~~or~~ veterinary food-animal drug ~~retailer~~ 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, ~~or~~ veterinary food-animal drug ~~retailer~~ 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, ~~or~~ veterinary food-animal drug ~~retailer~~ 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, ~~or~~ veterinary food-animal drug ~~retailer~~ retailer, or outsourcing facility is located, authorizing the board to enter the wholesaler, third-party logistics provider, pharmacy, ~~or~~ veterinary food-animal drug ~~retailer~~ 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, ~~or~~ veterinary food-animal drug ~~retailer.~~ 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.

Section 4316 is added to the Business and Professions Code, to read:

(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.

Section 4400 of the Business and Professions Code is amended to read:

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

(a) The fee for a nongovernmental pharmacy license shall be 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) 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.

~~(w)~~ (y) This section shall become ~~operative~~ inoperative on July 1, ~~2014.~~ 2017, and as of January 1, 2018, is repealed.

Section 4406 of the Business and Professions Code is amended to read:

All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the ~~State~~ Controller and at the same time the entire amount shall be paid into the State Treasury and shall be credited to the Pharmacy Board Contingent Fund which is

hereby created. This contingent fund shall be ~~for the use of the board and out of it and not otherwise shall be paid all expenses of the~~ available, upon appropriation of the Legislature, for the use of the board.

Other Business and Professions Code Sections

Section 208 of the Business and Professions Code is amended to read:

(a) Beginning April 1, 2014, a ~~CURES~~ 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.

~~(2)~~ (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.

~~(3)~~ (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.

~~(4)~~ (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).

Section 650 of the Business and Professions Code is amended to read:

(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.

~~(g)~~ (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).

Changes to Health and Safety Code

Section 11165 of the Health and Safety Code is amended to read:

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III,

and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third ~~party.~~ party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

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

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

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

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

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

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

(i) Materially falsifying an application for a subscriber.

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

(iii) Suspended or revoked federal DEA registration.

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

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

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

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

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

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

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

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

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

Section 11165.4 is added to the Health and Safety Code, to read:

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before

prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient, he or she shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before he or she prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason he or she did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within his or her control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department

shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) 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.

Section 150204 of the Health and Safety Code is amended to read:

(a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to ~~subdivision (a) of~~ Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in ~~paragraph (3) of subdivision (a) of Section 150201~~ Section 150201, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

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

(i) ~~Medication~~ (1) Except as provided in paragraph (2), medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the

eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(2) A pharmacy that exists solely to operate the repository and distribution program may repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date.

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

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

Section 56.10 of the Civil Code is amended to read:

(a) A provider of health care, health care service plan, or contractor shall not disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).

(b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:

(1) By a court pursuant to an order of that court.

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

(3) By a party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to Section 1987 of the Code of Civil Procedure, or any provision authorizing discovery in a proceeding before a court or administrative agency.

(4) By a board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.

(5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under Section 1282.6 of the Code of Civil Procedure, or another provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

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

(7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) By a medical examiner, forensic pathologist, or coroner, when requested in the course of an investigation by ~~the~~ a medical examiner, forensic pathologist, or coroner's office for the purpose of identifying the decedent or locating next of kin, or when investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant deaths, suspicious deaths, unknown deaths, or criminal deaths, or upon notification of, or investigation of, imminent deaths that may involve organ or tissue donation pursuant to Section 7151.15 of the Health and Safety Code, or when otherwise authorized by the decedent's representative. Medical information requested by ~~the~~ a medical examiner, forensic pathologist, or coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation or who is the prospective donor and shall be disclosed to ~~the~~ a medical examiner, forensic pathologist, or coroner without delay upon request. A medical examiner, forensic pathologist, or coroner shall not disclose the information contained in the medical record obtained pursuant to this paragraph to a third party without a court order or authorization pursuant to paragraph (4) of subdivision (c) of Section 56.11.

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to a person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, information so disclosed shall not be further disclosed by the recipient in a way that would violate this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of a provider of health care or a health care service plan may be reviewed by a private or public body responsible for licensing or accrediting the provider of health care or a health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in a way that would violate this part.

(6) The information may be disclosed to ~~the~~ a medical examiner, forensic pathologist, or county coroner in the course of an investigation by ~~the~~ a medical examiner, forensic pathologist, or coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b). A medical examiner, forensic pathologist, or coroner shall not disclose the information contained in the medical record obtained pursuant to this paragraph to a third party without a court order or authorization pursuant to paragraph (4) of subdivision (c) of Section 56.11.

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private

nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in a way that would disclose the identity of a patient or violate this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or a health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information shall not otherwise be disclosed by a health care service plan except in accordance with this part.

(11) This part does not prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Chapter 1 of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all of the requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Chapter 1 of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition, care, and treatment provided may be disclosed to a probate court investigator in the course of an investigation required or authorized in a conservatorship proceeding under the Guardianship-Conservatorship Law as defined in Section 1400 of the Probate Code, or to a probate court investigator, probation officer, or domestic relations

investigator engaged in determining the need for an initial guardianship or continuation of an existing guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, “tissue bank” and “tissue” have the same meanings as defined in Section 1635 of the Health and Safety Code.

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, including, but not limited to, the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems, or to disclosures made pursuant to subdivisions (b) and (c) of Section 11167 of the Penal Code by a person making a report pursuant to Sections 11165.9 and 11166 of the Penal Code, provided that those disclosures concern a report made by that person.

(15) Basic information, including the patient’s name, city of residence, age, sex, and general condition, may be disclosed to a state-recognized or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in a way that would violate this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to an entity contracting with a health care service plan or the health care service plan’s contractors to monitor or administer care of enrollees for a covered benefit, if the disease management services and care are authorized by a treating physician, or (B) to a disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, if the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan’s or contractor’s network of physicians. This paragraph does not require physician authorization for the care or treatment of the adherents of a well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(18) The information may be disclosed, as permitted by state and federal law or regulation, to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events, including, but not limited to, birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions, as authorized or required by state or federal law or regulation.

(19) The information may be disclosed, consistent with applicable law and standards of ethical conduct, by a psychotherapist, as defined in Section 1010 of the Evidence Code, if the psychotherapist, in good faith, believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a reasonably foreseeable victim or victims, and the disclosure is made to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

(20) The information may be disclosed as described in Section 56.103.

(21) (A) The information may be disclosed to an employee welfare benefit plan, as defined under Section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1002(1)), which is formed under Section 302(c)(5) of the Taft-Hartley Act (29 U.S.C. Sec. 186(c)(5)), to the extent that the employee welfare benefit plan provides medical care, and may also be disclosed to an entity contracting with the employee welfare benefit plan for billing, claims management, medical data processing, or other administrative services related to the provision of medical care to persons enrolled in the employee welfare benefit plan for health care coverage, if all of the following conditions are met:

(i) The disclosure is for the purpose of determining eligibility, coordinating benefits, or allowing the employee welfare benefit plan or the contracting entity to advocate on the behalf of a patient or enrollee with a provider, a health care service plan, or a state or federal regulatory agency.

(ii) The request for the information is accompanied by a written authorization for the release of the information submitted in a manner consistent with subdivision (a) and Section 56.11.

(iii) The disclosure is authorized by and made in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(iv) Any information disclosed is not further used or disclosed by the recipient in any way that would directly or indirectly violate this part or the restrictions imposed by Part 164 of Title 45 of the Code of Federal Regulations, including the manipulation of the information in any way that might reveal individually identifiable medical information.

(B) For purposes of this paragraph, Section 1374.8 of the Health and Safety Code shall not apply.

(22) Information may be disclosed pursuant to subdivision (a) of Section 15633.5 of the Welfare and Institutions Code by a person required to make a report pursuant to Section 15630 of the Welfare and Institutions Code, provided that the disclosure under subdivision (a) of Section 15633.5 concerns a report made by that person. Covered entities, as they are defined in Section 160.103 of Title 45 of the Code of Federal Regulations, shall comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule pursuant to subsection (c) of Section 164.512 of Title 45 of the Code of Federal Regulations if the disclosure is not for the purpose of public health surveillance, investigation, intervention, or reporting an injury or death.

(d) Except to the extent expressly authorized by a patient, enrollee, or subscriber, or as provided by subdivisions (b) and (c), a provider of health care, health care service plan, contractor, or corporation

and its subsidiaries and affiliates shall not intentionally share, sell, use for marketing, or otherwise use medical information for a purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by a patient or enrollee or subscriber or as provided by subdivisions (b) and (c), a contractor or corporation and its subsidiaries and affiliates shall not further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to a person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

(f) For purposes of this section, a reference to a "medical examiner, forensic pathologist, or coroner" means a coroner or deputy coroner as described in subdivision (c) of Section 830.35 of the Penal Code, or a licensed physician who currently performs official autopsies on behalf of a county coroner's office or a medical examiner's office, whether as a government employee or under contract to that office.

Regulation Changes

Changes to Regulations are made throughout the year. There are significant changes to the board's compounding regulations, Section 1735 et seq. and Section 1751 et seq. The language can be obtained from the following link - - http://www.pharmacy.ca.gov/laws_regs/1735_ooa_aprvd.pdf

Attachment 4

Advanced Practice Pharmacist

16 CCR § 1730.2

Title 16. Board of Pharmacy
Order of Adoption

Add Section 1730.2 of Article 3. of Division 17 of Title 16 of the California Code of Regulations as follows:

§ 1730.2 Certification Programs

(a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned.

(b) For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:

(1) The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;

(2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant's understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;

(3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:

(A) An advanced practice pharmacist licensed by the board or

(B) An expert with experience in the respective area(s) of focus specified in subparagraph (1), where "expert" means a person who qualifies to teach at a school of pharmacy recognized by the board.

(4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and

(5) The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.

Note: Authority cited: Section 4005 and 4210, Business and Professions Code.
Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.

Attachment 5

Immunizations / Vaccinations

16 CCR § 1746.4

BOARD OF PHARMACY

Order of Adoption

Add and Adopt §1746.4, which is new regulation text as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Completion of an approved immunization training program, and

(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a

vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code, Section 120440, Health and Safety Code, and Sections 300aa – 25, Title 42, United States Code.

Virginia Herold
Executive Officer
California State Board of Pharmacy

Attachment 6

Compounding
16 CCR § 1735 and 1751 et seq.

Board of Pharmacy

Order of Adoption

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) ~~for oral, rectal, topical, or injectable administration~~, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

~~(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace~~

~~(d)~~(c) The parameters and requirements stated by ~~this~~ Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug

products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) "Displacement airflow method" means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) "Integrity" means retention of potency until the ~~expiration~~ beyond use date ~~noted~~ provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active

ingredient(s).

(u) “Media-fill test” means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

(y) “Potency” means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber’s practice environment.

(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for

compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, ~~and~~ the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) "Strength" means amount of active ingredient per unit of a compounded drug ~~product~~

preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~i~~Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration ~~or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber~~; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or

for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) ~~for~~ With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, ~~taken as a whole,~~ is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug ~~product~~ preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

~~(d)~~(e) A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula ~~record~~ document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(e)~~(f) Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f)~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until ~~it~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(g)~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

~~(h)~~(i) Every compounded drug ~~product~~ preparation shall be given a~~n expiration~~ beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.~~, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This "beyond use date" of the compounded drug product~~ shall not exceed any of the following: ~~180 days from preparation or~~

(A) the shortest expiration date or beyond use date of any ~~component~~ ingredient in the compounded drug ~~product~~ preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) 180 days for non-aqueous formulations,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be ~~using the same~~ identical ~~components~~ in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

~~(i)~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

~~(j)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed

by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile ~~injectable~~ compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.

(a) For each compounded drug ~~product~~ preparation, ~~the~~ pharmacy records shall include:

(1) The master formula ~~record~~ document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug ~~product~~ preparation was compounded.

~~(3)~~(C) The identity of ~~the~~ any pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation.

~~(4)~~(D) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

~~(5)~~(E) The quantity of each ~~component~~ ingredient used in compounding the drug ~~product~~ preparation.

~~(6)~~(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile ~~products~~ preparations compounded ~~on a one-time basis~~ in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (~~35~~ 37th Revision, Effective ~~May~~ December 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~.

~~(7)~~(G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product~~ preparation.

~~(8)~~(H) The ~~expiration~~ beyond use date or beyond use date and time of the final compounded drug ~~product~~ preparation, expressed in the compounding document in a standard date and time format.

~~(9)~~(I) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other ~~C~~chemicals, bulk drug substances, and drug products~~, and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from ~~reliable~~ FDA- registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products~~, and components~~ used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was ~~created~~ last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

~~In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s).~~

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. ~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration date.~~

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain ~~a~~ written polic~~y~~ies and procedures ~~manual~~ for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The polic~~y~~ies and procedures ~~manual~~ shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. ~~and~~ The policies and procedures shall be updated whenever changes in policies and procedures ~~processes~~ are implemented.

(c) The polic~~y~~ies and procedures ~~manual~~ shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes or to the~~ polic~~y~~ies or procedures ~~manual~~.

(2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent ~~verification~~ information demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) ~~The p~~ Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(~~4~~5) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.

(~~5~~6) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded ~~in writing~~ in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process. ~~Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.~~

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing ~~analysis of compounded drug products~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collated~~ maintained along with the compounding log ~~record~~ and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be ~~below~~ outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range

temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile ~~Injectable~~ Compounding

1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug ~~products~~ preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

(1) ~~Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified

technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

~~(5)~~ (2) ~~The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable~~ drug ~~products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)~~ (3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

~~(7)~~ (4) There shall be a refrigerator and, ~~/or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

~~(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b)~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, any pharmacy engaged in any compounding of ~~for~~ sterile drug ~~products~~ preparations ~~compounded from one or more non-sterile ingredients,~~ shall maintain the following records, which must be ~~must be made and kept by~~ readily retrievable, within the pharmacy:

(1) ~~The~~ Documents evidencing training and competency evaluations of employees in sterile ~~product~~ drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

(6) Documents indicating daily documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity

measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control ~~logs~~ records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of ~~I~~inspections for expired or recalled ~~pharmaceutical products or raw ingredients~~ chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document ~~work sheet~~, the preparation compounding log ~~work sheet~~, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy ~~which~~ that compounds sterile ~~injectable~~ drug ~~products~~ preparations shall include the following information on the label~~s~~ for each such ~~those products~~ preparation:

(a) The ~~T~~telephone number of the pharmacy. ~~, except~~ The telephone number is not required on the label for sterile ~~injectable~~ drug ~~products~~ preparations ~~dispensed~~ administered ~~for~~ to inpatients ~~of a~~ within the hospital ~~pharmacy~~.

~~(b) Name and concentration of ingredients contained in the sterile injectable drug product.~~

(~~c~~b) Instructions for storage, ~~and~~ handling, and administration.~~:~~

(~~d~~c) All ~~cytotoxic~~ hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "~~Cytotoxic~~ Hazardous – Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile ~~Injectable~~ Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove

fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written

policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedures manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:~~

~~(1) Compounding, filling, and labeling of sterile injectable compounds.~~

~~(2) Labeling of the sterile injectable product compounded drug preparations based on the intended route of administration and recommended rate of administration.~~

~~(3) Equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable products.~~

~~(5) Procedures for handling cytotoxic agents.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~

~~(c) Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues. The written policies and procedures shall describe the pharmacy~~

~~protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

~~(I)~~(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following: ~~must be established for the use of master formulas and work sheets and for appropriate documentation.~~

~~(J)~~(1) Process validation for chosen ~~S~~ sterilization methods.

~~(K)~~(2) End-product evaluation, quantitative, and qualitative testing.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

(d)~~(1) All written p~~Policies and procedures shall be immediately available to all personnel involved in ~~these~~ compounding activities and to board inspectors.

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding sterile ~~injectable products~~ drug preparations.~~, and any~~ All personnel involved must read all additions, revisions, and deletions to the written policies and procedures ~~must be communicated to all personnel involved in sterile compounding~~. Each review must be documented by a signature and date.

~~(3) Policies and procedures must address at least the following:~~

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area.~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.

(a) No sterile ~~injectable~~ drug ~~product~~ preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable~~ drug ~~products~~ preparations.

(b) During the compounding of ~~preparation of~~ sterile ~~injectable~~ drug ~~products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be

cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following

criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing ~~parenteral cytotoxic~~ sterile hazardous agents shall do so in accordance with Section 505.~~12~~5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair

cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile ~~Injectable~~ Compounding Attire.

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b)~~ (a) When compounding sterile drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low~~ non-shedding ~~coverall~~ gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

~~(3)~~ (4) Compounding personnel shall not wear any wrist, ~~H~~hand, finger, ~~and~~ or ~~wrist~~ other visible ~~jewelry must be eliminated~~ jewelry, piercing, headphones, earbuds, or personal electronic device. ~~If jewelry cannot be removed then it must be thoroughly cleaned and covered with a~~

~~sterile glove.~~

(~~4) Head and facial hair must be kept out of the critical area or be covered.~~

(5) ~~Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ **Sterile Compounding Consultation; Training of Sterile Compounding Staff**.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile ~~injectable~~ drug ~~products~~ preparations and related

supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug ~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations.

(e) Pharmacies that compound sterile drug ~~products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices

using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

(1) Procedures for ~~C~~cleaning and sanitization of the ~~parenteral medication~~ sterile preparation area.

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

~~(3)~~(2) Actions to be taken in the event of a drug recall.

~~(4)~~(3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates

for compounded sterile ~~injectable~~ drug ~~products~~ preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable products must first successfully~~

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

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

~~(c)~~ (e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits,

before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

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

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package

containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.

In any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.10.~~ 1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

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

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.11.~~ 1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy

may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy~~y~~ies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

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

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section ~~1751.11~~ 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section ~~1751.11~~ 1753.

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

Virginia Herold
Executive Officer
California State Board of Pharmacy

Attachment 7

Advanced Practice Pharmacist

16 CCR § 1730, 1730.1 & 1749

Title 16. BOARD OF PHARMACY
Third Modified Text

Changes made to the originally proposed language in the first modified text are shown by ~~double strikethrough~~ for deleted language and **bold and dashed underline** for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the proposed language in the second modified text are shown by ~~**double-strikethrough and bold underline**~~ for deleted language and **bold and double underline** for added language. (Additionally, the modified text is listed in blue for color printers.)

Changes made to the proposed language in this third modified text are shown by ~~**double-strikethrough and bold wavy underline**~~ for deleted language and **bold wavy underline** for added language. (Additionally, the modified text is listed in purple for color printers.)

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210**, subdivision** (a)(2)(A).

Note: Authority cited: Section**s** 4005 **and**~~,~~ 4210 ~~**and 4400**~~, Business and Professions Code. Reference: Section~~**s 4052.6,**~~ 4210~~**and 4400**~~, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of **Business and Professions Code section** 4210**,** an applicant for advanced practice pharmacist licensure must satisfy two of the following sub**section**~~**division**~~s.

> ~~**(a)**~~ **(1)** Demonstrate possession of a current certification as specified in Business and Professions Code section 4210**, subdivision** (a)(2)(A)~~**, an applicant shall**~~ **by** provid**ing**~~**e**~~ either:
>
> > ~~**(1)**~~ **(A)** A copy of the certification award that includes the name of the

applicant pharmacist, the area of specialty and date of completion, or

~~(2)~~ (B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

~~(b)~~ (2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B)~~, an applicant shall~~ by providinge either:

~~(1)~~ (A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

~~(2)~~ (B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion~~, and area(s) of specialty~~. For an applicant whothat cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection ~~(2)~~.

~~(c)~~ (3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must ~~be composed of~~ include no fewer than 1,500 hours of experience providing clinical services to patients~~, and must be earned within four consecutive years~~. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or ~~and~~ discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

~~(1)~~ (A) A written statement from the applicant attesting under penalty of perjury that he or she has:

~~(A)~~ (i) Earned the clinical experience within the required time frame; and

~~(B)~~ (ii) Completed the required number of hours of experience providing clinical services to patients, as specified in ~~this subdivision~~ subsection (a)(3), ~~and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and~~

~~(i)~~ (I)The applicant shall provide a copy of the collaborative practice agreement or protocol.

~~(ii)~~(II)If a copy of the collaborative practice agreement or protocol

is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

~~(2)~~ **(B)** A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least ~~one year~~ **1,500 hours** of experience providing clinical services to patients. **For an applicant who~~that~~ cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection~~(2)~~.**

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Section**s** 4005~~,~~ **and** 4210 ~~**and 4400**~~, Business and Professions Code. Reference: Section**s** 4052.1, 4052.2~~,~~ **and** ~~**4052.6,**~~ 4210 ~~**and 4400**~~, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, **4210,** 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*

(g)(1) The fee for the biennial renewal of a pharmacist's license is **one hundred ninety-five dollars ($195)** ~~two hundred seven dollars ($207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165). The penalty for failure to renew is eighty two dollars fifty cents ($82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195). The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(*l*) The fee for an intern pharmacist license is one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) . The penalty for failure to renew is one hundred fifty dollars ($150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195). The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

Attachment 8

Travel Medications

16 CCR § 1746.5

BOARD OF PHARMACY

Second Modified Text

Changes made to the originally proposed language are shown by ~~single strikethrough~~ for deleted language and single underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the modified proposed language are shown by ~~double strikethrough~~ for deleted language and bold and double underline for added language. (Additionally, the modified text is listed in blue for color printers.)

Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications "not requiring a diagnosis" means a prescription medication that is either:

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization ~~certification~~ certificate program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(~~1~~2) Completion of an ~~approved~~ travel medicine training program, which must consist of at least 10 ~~20~~ hours of training and cover each medication related element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),

(~~2~~3) Completion of the CDC Yellow Fever Vaccine Course, and

(~~3~~4) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of ~~dispense~~ furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.8, Business and Professions Code.

Attachment 9

Disciplinary Guidelines

16 CCR § 1760

California State Board of Pharmacy
Specific Language to Amend 16 CCR § 1760

Initial proposed changes indicated with single ~~strikethrough~~ for deletions and single underline for additions.

Modified changes indicated with ~~double strikethrough~~ for deletions and double underline for additions

Amend Section 1760 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

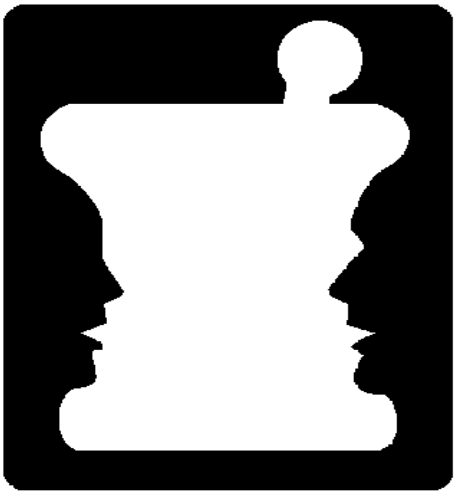
§ 1760. Disciplinary Guidelines.
In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~10/2007 7/2015~~ 10/2015), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation-the presence of mitigating factors; the age of the case; evidentiary problems.

Note: Authority cited: Sections 315, 315.2, 315.4 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 4300 - 4313 ~~and 4301~~, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines
and Model Disciplinary Orders



BE AWARE & TAKE CARE:
Talk to your pharmacist!

California State Board of Pharmacy
Department of Consumer Affairs
(Rev. ~~10/2007~~ ~~7/2015~~ 10/2015)

STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

~~**William Powers**~~
Amy Gutierrez
PRESIDENT

Virginia K. Herold
EXECUTIVE OFFICER

1625 N. Market Blvd, Suite N-219
Sacramento, CA 95834
(916) 574-7900
(916) 574-8618 Fax
www.pharmacy.ca.gov

Additional copies of these disciplinary guidelines
may be downloaded from the board's website

BOARD OF PHARMACY

DISCIPLINARY GUIDELINES

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DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES
(Rev. ~~10/2007~~ ~~7/2015~~ 10/2015)

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- protecting the health, safety, and welfare of the people of California;
- advocating the highest quality of affordable pharmaceutical care;
- providing the best available information on pharmaceutical care; and
- promoting education, wellness and quality of life.

Pharmacists and intern pharmacists are patient advocates and vital members of the clinical care team who provide pharmaceutical care and exercise clinical judgment ~~for the citizens of California~~ for their patients~~,~~. They also exercise critical vigilance and control over medication stocks, drug inventories, and quality assurance protocols. Pharmacy technicians provide crucial assistance to pharmacists and intern pharmacists in all of their pharmacy tasks. Pharmacists and intern pharmacists enlighten their patients ~~enlightening them~~ about their drug ~~therapy~~ therapies through effective communicating and listening, assessing, collaborating, understanding and intervening. They also, under appropriate conditions, initiate or terminate drug therapies, compound drug preparations, ensure safety and security of drug stocks, and otherwise contribute to clinical safety and performance. Also, pharmacists and intern pharmacists are always vigilant to ensure that drug therapies are being appropriately and effectively utilized. When a pharmacist takes on the responsibility of a pharmacist-in-charge, the pharmacist also ensures the pharmacy's compliance with state and federal law, quality assurance responsibilities, and inventory controls. Likewise, the premises and other individuals licensed by the board help to ensure the reliability, safety, and security of the dangerous drug and/or dangerous device supply chain, so that patients and prescribers can be confident in the drugs or devices prescribed. Enforcement officials act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and/or dangerous devices and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with Section 1760 of the California Code of Regulations, and the provisions contained in Sections 1771-1774, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, board licensees, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, ~~board licensees~~, the courts, board staff, and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III or IV violations are involved.

In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not ~~upon~~ on the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works~~, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel~~. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board. Typically, the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel.

For purposes of these guidelines, "board" includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
15. financial benefit to the respondent from the misconduct.
16. ~~consideration of~~ other licenses held by the respondent and license history of those licenses.
17. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (see Business and Professions Code Section 315)

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he, ~~or~~ she, or it has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

a. Recent, dated, written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice ~~of pharmacy~~ relevant to the disciplinary proceeding, including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
b. Recent, dated, letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
c. Recent, dated, letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
d. Recent, dated, laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
e. Recent, dated, physical examination/ ~~or~~ assessment report(s) by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such ~~assessments and~~ report(s) will be subject to verification by board staff.
f. Recent, dated, letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.
g. Recent, dated, letters from persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the respondent's character; the respondent's rehabilitation, if any; the conduct of which the respondent is accused; or any other pertinent facts that would enable the board to better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.
h. For premises licensees, recent, dated letters from appropriate licensees or representatives of licensees of the board in good standing, or from appropriate consultants and/or experts in the field, written by persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the character and rehabilitation, if any, of respondent's owner(s), officer(s), or managerial employee(s); the conduct of which the respondent is accused; the details of respondent's operation(s); or any other pertinent facts that would enable the board to

better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.

TERMS OF PROBATION – ~~PHARMACIST/INTERN PHARMACIST~~ INDIVIDUAL LICENSEES (PHARMACIST, ADVANCED PRACTICE PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE AND DESIGNATED REPRESENTATIVE-3PL)

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate ~~where self-administration or diversion of controlled substances is involved~~ in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension. The board ~~is~~ also ~~guided by~~ uses the Uniform Standards Regarding Substance-Abusing Licensees developed by the Substance Abuse Coordinating Committee of the Department of Consumer Affairs (2011). ~~Where appropriate and to the extent practicable, the terms and conditions that are specified below incorporate and/or are impacted by those Uniform Standards.~~

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against the license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

For those licenses issued to individuals (pharmacists, intern pharmacists, pharmacy technicians, and designated representatives, designated representatives-3PL, and advanced practice pharmacists), the board has identified four (4) categories of violations and their associated recommended minimum and maximum penalties. These categories of violations are arranged in ascending order from the least serious (Category I) to the most serious (Category IV), although any single violation in any category, or any combination of violation(s) in one or more categories, may merit revocation. For pharmacy technicians and designated representatives, the board believes an order of revocation is typically the appropriate penalty when any grounds for discipline are established, and that if revocation is not imposed that a minimum Category III level of discipline should be imposed.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses~~.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive.~~ For

each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation ~~of each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; ~~one~~ two years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations ~~which are~~ that are less serious ~~that~~ than Category 2 through 4 but are potentially harmful. These may include:

- violations ~~which are relatively minor but are potentially harmful~~ of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- ~~repeated violations of a relatively minor nature:~~ smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices, or controlled substances; and
- violation(s) of packaging requirements, security control requirements, or reporting requirements.
- violation(s) involving the improper compounding of drug products
- violation(s) resulting from the misuse of education or licensing privileges irrespective of whether it occurs outside of an entity licensed by the board.

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4052.1 Skin Puncture by Pharmacist; Conditions Permitting~~
~~4052.5 Pharmacist May Select Different Form of Medication with Same Active Chemical~~

~~Ingredients; Exceptions~~
~~4052.7 Repackage Previously Dispensed Drugs; Requirements~~
~~4053 Exemptee Supervisor of Manufacturer, etc.: Requirements~~
~~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~~
~~4062 Furnishing Dangerous Drugs During Emergency~~
~~4064 Emergency Refill of Prescription Without Prescription Authorization~~
~~4065 Injection Card System; Requirements of Administration~~
~~4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel~~
~~4068 Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements~~

~~Article 4. Requirements for Prescription~~

~~4070 Reduction of Oral or Electronic Prescription to Writing~~
~~4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded~~
~~4072 Oral or Electronic Transmission of Prescription – Health Care Facility~~
~~4073 Substitution of Generic Drug – Requirements and Exceptions~~
~~4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications~~
~~4076 Prescription Container – Requirements for Labeling~~
~~4077 Dispensing Dangerous Drug in Incorrectly Labeled Container~~

~~Article 5. Authority of Inspectors~~

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

~~Article 6. General Requirements~~

~~4100 Change of Address or Name – Notification to Board~~
~~4103 Blood Pressure – Taking by Pharmacist~~

~~Article 7. Pharmacies~~

~~4114 Intern Pharmacist: Activities Permitted~~
~~4119 Furnish Prescription Drug to Licensed Health Care Facility – Secured~~
~~4119.1 Pharmacy May Provide Services to Health Facility~~
~~4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy~~
~~4121 Advertisement for Prescription Drug: Requirements; Restrictions~~
~~4122 Required Notice at 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~~

~~Article 9. Hypodermic Needles and Syringes~~

~~4141 Furnishing Without License~~
~~4142 Prescription Required~~
~~4143 Exemption: Sale to Other Entity, Physician, etc.~~
~~4144 Industrial Use Exception~~

~~4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions~~
~~4148 Confiscation if Found Outside Licensed Premises~~
~~4149 Sale by Distributor~~

~~Article 10. Pharmacy Corporations~~

~~4151 Licensure Requirements~~
~~4152 Corporate Name Requirements~~
~~4153 Shareholder Income While Disqualified~~
~~4156 Unprofessional Conduct by Corporation~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~
~~4162 Issuance or Renewal of Wholesaler License; Surety Bond~~
~~4163 Unauthorized Furnishing by Manufacturer or Wholesaler~~
~~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~~
~~4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises~~

~~Article 13. Non-Profit or Free Clinics~~

~~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 Prohibited~~
~~4186 Automated Drug Delivery Systems~~

~~Article 14. Surgical Clinics~~

~~4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required~~
~~4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs~~
~~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~~

~~Article 15. Veterinary Food-Animal Drug Retailers~~

~~4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area~~
~~4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers~~
~~4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist~~

~~Article 17. Continuing Education~~

~~4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee~~
~~4232 Content of Course~~

~~Article 18. Poisons~~

~~4240 Application of Act~~

~~Article 20. Prohibitions and Offenses~~

~~4341 Advertisement of Prescription Drugs or Devices~~
~~4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1704 Change of Address~~
~~1705 Notification of Bankruptcy, Receivership or Liquidation~~
~~1708.2 Discontinuance of Business~~
~~1708.4 Pharmacist Handling Radioactive Drugs~~
~~1708.5 Pharmacy Furnishing Radioactive Drugs~~
~~1709 Names of Owners and Pharmacist in Charge~~
~~1712 Use of Pharmacist Identifiers~~
~~1714 Operational Standards and Security~~
~~1715.6 Reporting Drug Loss~~
~~1716 Variation From Prescriptions~~
~~1717 Pharmaceutical Practice~~
~~1717.1 Common Electronic Files~~
~~1717.4 Electronic Transmission of Prescriptions~~
~~1718.1 Manufacturer's Expiration Date~~
~~1726 Supervision of Intern Pharmacists~~
~~1728 Requirements for Examination~~
~~1732.1 Requirements for Accredited Providers~~
~~1732.3 Requirements for Continuing Education Courses~~
~~1732.4 Provider Audit Requirements~~
~~1732.5 Renewal Requirements for Pharmacist~~
~~1744 Drug Warnings~~
~~1746 Emergency Contraception~~
~~1751 Sterile Injectable Compounding Area~~
~~1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients~~
~~1751.02 Policies and Procedures~~
~~1751.1 Laminar Flow Biological Safety Cabinet~~
~~1751.2 Labeling Requirements~~
~~1751.3 Recordkeeping Requirements~~
~~1751.4 Attire~~
~~1751.5 Training of Staff, Patient, and Caregiver~~
~~1751.6 Disposal of Waste Material~~

~~1751.7 Quality Assurance and Process Evaluation~~
~~1751.9 Reference Materials~~
~~1751.11 Furnishing to Home Health Agencies and Licensed Hospices~~
~~1751.12 Obligations of a Pharmacy Furnishing Portable Containers~~
~~1771 Posting Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1780 Minimum Standards for Wholesalers~~
~~1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers~~
~~1781 Exemption Certificate~~
~~1786 Exemptions~~
~~1787 Authorization to Distribute Hemodialysis Drugs and Devices~~
~~1790 Assembling and Packaging~~
~~1791 Labeling~~
~~1792 Receipt for Shipment~~

~~HEALTH AND SAFETY CODE~~

~~11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties~~
~~11100.1 Report of Chemicals Received from Outside State; Penalties~~
~~11151 Limitation on Filling Prescriptions From Medical Students~~
~~11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration~~
~~11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years~~
~~11159.1 Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years~~
~~11159.2 Exception to Triplicate Prescription Requirement~~
~~11167 Emergency Dispensing of Schedule II Substance: Circumstances and Requirements~~
~~11167.5 Oral or Electronic Prescriptions for Scheduled II Controlled Substances for Specified Inpatients, Residents, and Home Hospice Patients; Requirements~~
~~11171 Prescribing, etc. Controlled Substance Only as Authorized~~
~~11172 Antedating or Postdating Prescription Prohibited~~
~~11175 Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription~~
~~11180 Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription~~
~~11200 Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred~~
~~11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements~~
~~11205 Maintenance and Retention of Records in Separate File~~
~~11206 Required information on Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed~~
~~11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form~~
~~11251 Authorized Wholesale Sale by Pharmacists~~
~~11252 Preservation of Federally Required Forms~~
~~11253 Duration of Retention~~
~~11255 Actions Constituting Sale~~
~~11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer~~
~~111225 to~~

~~111655 Adulterated or Misbranded Drugs or Devices~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1301.11 Persons required to register.~~
~~1301.12 Separate registrations for separate locations.~~
~~1301.71 Security requirements generally.~~
~~1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.~~
~~1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.~~
~~1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.~~
~~1301.75 Physical security controls for practitioners.~~
~~1301.76 Other security controls for practitioners.~~
~~1301.90 Employee screening procedures.~~
~~1301.91 Employee responsibility to report drug diversion.~~
~~1301.92 Illicit activities by employees.~~
~~1302.03 Symbol required; exceptions.~~
~~1302.04 Location and size of symbol on label and labeling.~~
~~1302.05 Effective dates of labeling requirements.~~
~~1302.06 Sealing of controlled substances.~~
~~1302.07 Labeling and packaging requirements for imported and exported substances.~~
~~1304.11 Inventory requirements.~~
~~1304.21 Inventories of importers and exporters~~
~~1304.31 Reports from manufacturers importing narcotic raw materials.~~
~~1304.32 Reports of manufacturers importing coca leaves.~~
~~1304.33 Reports to ARCOS.~~
~~1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.~~
~~1305.04 Persons entitled to order Schedule I and II controlled substances.~~
~~1305.05 Power of attorney.~~
~~1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.~~
~~1305.11 Procedure for obtaining DEA Forms 222.~~
~~1305.12 Procedure for executing DEA Forms 222.~~
~~1305.14 Procedure for endorsing DEA Forms 222.~~
~~1305.15 Unaccepted and defective DEA Forms 222.~~
~~1305.16 Lost and stolen DEA Forms 222.~~
~~1306.03 Persons entitled to issue prescriptions.~~
~~1306.05 Manner of issuance of prescriptions.~~
~~1306.14 Labeling of substances and filling of prescriptions.~~
~~1306.24 Labeling of substances and filing of prescriptions.~~
~~1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.~~
~~1306.26 Dispensing without a prescription.~~
~~1307.11 Distribution by dispenser to another practitioner or reverse distributor.~~
~~1307.12 Distribution to supplier or manufacture.~~
~~1307.13 Incidental manufacture of controlled substances.~~
~~1307.21 Procedure for disposing of controlled substances.~~
~~1700.1 to~~
~~1707.15 Child-resistant containers.~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation ~~where self-administration or diversion of controlled substances is involved~~ in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for violation(s) with serious potential for harm, as well as for violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competence, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices, or controlled substances;
- violation(s) of law governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including smaller cases of diversion or self-administration or abusive use of a controlled substance, dangerous drug and/or dangerous device, or alcohol;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles and syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet without valid prescription(s);
- purchasing, trading, selling, or transferring dangerous drug(s) and/or dangerous device(s) to or from unauthorized person(s);
- failure(s) to make required reports to the board or other regulatory agencies, including CURES obligations and reporting to DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, ~~clearly~~ excessive furnishing of controlled substances, moral turpitude, dishonesty, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances;
- violating, or assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and

- subverting or attempting to subvert an investigation conducted by the board.
- repeated violation(s) involving the improper compounding of drug products
- violations resulting from the misuse of education or licensing privileges irrespective of whether these violations occur in a entity regulated by the board.
- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~650 Rebates or Discounts for Referral Prohibited~~
~~650.1 Lease Prohibition – Hospitals or Prescribers~~
~~651 Professional Advertising Requirements~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4051(b) Conduct Authorized by Pharmacist~~
~~4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider~~
~~4060 Controlled Substance – Prescription Required; Exceptions~~
~~4061 Distribution of Drug as Sample; Written Request Required~~
~~4063 Refill of Prescription for Dangerous Drug or Device; Prescriber Authorization~~
~~4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription~~
~~4075 Proof of Identity Required – Oral or Electronic Prescription~~
~~4078 False or Misleading Label on Prescription~~

~~**Article 6. General Requirements**~~

~~4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board~~
~~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~~

~~**Article 7. Pharmacies**~~

~~4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation~~
~~4113 Pharmacist in Charge: Notification to Board; Responsibilities~~
~~4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios~~
~~4115.5 Pharmacy Technician Trainee; Placement; Supervisions; 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~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents~~

~~**Article 9. Hypodermic Needle and Syringes**~~

~~4140 Unlawful Possession~~
~~4147 Disposal of Needle or Syringe~~

~~**Article 11. Wholesalers and Manufacturers**~~

~~4160 Wholesaler: License Required~~
~~4163 Unauthorized Furnishing by Manufacturer or Wholesaler~~
~~4164 Reports Required~~
~~4169(a)(1) Prohibited Acts~~

~~**Article 13. Non-Profit of Free Clinics**~~

~~4185 Inspection Permitted~~

~~**Article 14. Surgical Clinics**~~

~~4195 Inspection Permitted~~

~~**Article 19. Disciplinary Proceedings**~~

~~4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l)-(q)~~
~~4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder~~
~~4303 Nonresident Pharmacy: Grounds for Discipline~~
~~4304 Out-of-state Distributor: Authority to Discipline~~
~~4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist~~
~~4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee~~
~~4306 Violation of Professional Corporation Act as Unprofessional Conduct~~
~~4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct~~

~~**Article 20. Prohibitions and Offenses**~~

~~4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another~~
~~4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist~~
~~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 Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee~~
~~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 as Misdemeanor~~
~~4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions~~
~~4381 Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce~~
~~4382 Board May Audit Sales to Walk-in Customers~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)~~
~~1707.2 Notice to Consumers and Duty to Consult~~
~~1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery~~
~~1709.1 Designation of Pharmacist in Charge~~
~~1714.1 Pharmacy Operations During the Temporary Absence of a Pharmacist~~
~~1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge~~
~~1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions~~
~~1716.1 Compounding Unapproved Drugs for Prescriber Office Use~~
~~1716.2 Record Requirements-Compounding for Future Furnishing~~
~~1717.3 Preprinted, Multiple Checkoff Prescription Blanks~~
~~1723.1 Confidentiality of Examination Questions~~
~~1745 Partial Filling of Schedule II Prescriptions~~
~~1751.10 Furnishing to Parenteral Patient at Home~~
~~1761(a) Erroneous or Uncertain Prescriptions~~
~~1764 Unauthorized Disclosure of Prescriptions~~
~~1765 Commissions, Gratuities, and Rebates~~
~~1766 False or Misleading Advertising~~
~~1775.3 Compliance with Orders of Abatement~~
~~1782 Reporting Sales of Drugs Subject to Abuse~~
~~1783 Manufacturer or Wholesaler Furnishing Drugs or Devices~~
~~1793.1 Duties of a Pharmacist~~
~~1793.2 Duties of a Pharmacy Technician~~
~~1793.3 Other Non-Licensed Pharmacy Personnel~~
~~1793.7 Requirements for Pharmacies Employing Pharmacy Technicians~~
~~1793.8 Technicians in Hospitals with Clinical Pharmacy Programs~~

~~HEALTH AND SAFETY CODE~~

~~11103 Report of Theft, Loss, or Shipping Discrepancy~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11152 Nonconforming Prescriptions Prohibited~~
~~11154 Prescription, etc, Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.~~
~~11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized~~
~~11164 Prescriptions for Schedule II, III, IV and V Controlled Substances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances~~
~~11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited~~
~~11170 Prohibition on Prescribing, etc. Controlled Substance for Self~~
~~11179 Retention of Controlled Substance Prescription~~

~~11207 Only Pharmacist or Intern Authorized to Fill Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11350 Possession of Specified Controlled Substance~~
~~11377 Unlawful Possession of Specified Substance~~
~~11165(d) CURES Transmission~~
~~150204 Surplus Medication Collection and Distribution Program~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1304.03 Persons required to keep records and file reports.~~
~~1304.04 Maintenance of records and inventories.~~
~~1304.11 Inventory requirements .~~
~~1304.21 General requirements for continuing records.~~
~~1304.22 Records for manufacturers.~~
~~1305.07 Special procedure for filling certain orders.~~
~~1305.13 Procedure for filling DEA Forms 222.~~
~~1306.04 Purpose of issue of prescription.~~
~~1306.06 Persons entitled to fill prescriptions.~~
~~1306.07 Administering or dispensing of narcotic drugs.~~
~~1306.11 Requirement of prescription.~~
~~1306.12 Refilling prescription.~~
~~1306.13 Partial filling of prescriptions.~~
~~1306.21 Requirement of prescription.~~
~~1306.22 Refilling of prescriptions.~~
~~1306.23 Partial filling of prescriptions.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation ~~where self-administration or diversion of controlled substances is involved~~ in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by ~~track and trace, pedigree, transaction history~~ Drug Supply Chain Security Act requirements, and other similar requirements for dangerous drugs and/or dangerous devices;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;

- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- violation(s) of laws governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including repeat or serious diversion or self-administration, or abuse;
- violation(s) of law governing self-administration of controlled substances that ~~could lead to~~ create a potential infection control risk.
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet,
  without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) and/or dangerous device(s);
- resale(s) of preferentially priced drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) and/or dangerous device(s) or controlled substance(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
  - ~~most criminal convictions involving dangerous drugs or controlled substances~~
  - ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
  - ~~fraudulent acts committed in connection with the licensee's practice~~
  - ~~drug shortages~~
  - ~~violation of a licensee's corresponding responsibility.~~
- repeat or serious violation(s) involving the improper compounding of drug products
- repeat or serious violation(s) resulting from the misuse of education or licensing privileges irrespective of whether ~~is~~ it occurs outside of an entity licensed by the board.

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4034 Pedigree~~
~~4051(a) Conduct Limited To Pharmacist~~
~~4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions~~
~~4059.5 Who May Order Dangerous Drugs or Devices: Exceptions~~

~~Article 5. Authority of Inspectors~~

~~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~~
~~4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device~~

~~Article 6. General Requirements~~

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

~~Article 7. Pharmacies~~

~~4110 Licensed Required; Temporary Permit Upon Transfer of Ownership~~
~~4111 Restrictions on Prescriber Ownership~~

~~Article 11. Wholesalers and Manufacturers~~

~~4169(a)(2) to~~
~~4169(a)(5) Prohibited Acts~~

~~Article 15. Veterinary Food-Animal Retailers~~

~~4199 Labeling Requirements; Maintaining Prescription Records~~

~~Article 19. Disciplinary Proceedings~~

~~4301 Unprofessional Conduct - subsections (i) - (k) and (o)~~
~~4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding~~
~~4308 Prohibited Association: Notification of Affected Licensees Known to Board~~

~~Article 20. Prohibitions and Offenses~~

~~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~~
~~4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages~~
~~4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs~~
~~4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records~~

~~4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor~~
~~4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707 Waiver Requirements for Off-Site Storage of Records~~
~~1718 Current Inventory Defined~~
~~1761(b) Erroneous or Uncertain Prescriptions~~
~~1771 Posting of Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1773 Disciplinary Conditions of Probation of Pharmacist~~
~~1774 Disciplinary Conditions of Probation of Permit~~

~~HEALTH AND SAFETY CODE~~

~~11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~
~~11105 False Statement in Report~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation~~
~~11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy~~
~~11157 No False or Fictitious Prescriptions~~
~~11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty~~
~~11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label~~
~~11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.~~
~~11351 Possession or Purchase for Sale of Specified Controlled Substance~~
~~11368 Forged or Altered Prescriptions~~
~~11375 Possession for Sale or Selling Specified Substance~~
~~11378 Possession for Sale~~
~~11550 Using or Being Under Influence of Controlled Substance~~
~~11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility~~
~~111295 Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device~~
~~111300 Unlawful to Adulterate a Drug~~
~~111305 Unlawful to Receive in Commerce an Adulterated Drug~~
~~111440 Unlawful Manufacturer, Selling a Misbranded Drug~~
~~111445 Unlawful for a Person to Misbrand~~
~~111450 Unlawful to Receive into Commerce a Drug that is Misbranded~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (~~R~~revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include: ~~the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:~~

- ~~possession for sale~~ violations involving possession for sale, transportation, importation, and/or use of a minor for unlawful sale of controlled substances;
- ~~transportation~~ criminal convictions involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices, or controlled substances; ~~and~~
- repeated or serious example(s) of conduct described in Category I, Category II, or Category III.
- violation(s) of law governing self-administration of controlled substances that ~~could lead to~~ create a potential infection control risk.
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when:~~ where a respondent fails to file a notice of defense to an Accusation or Petition to Revoke Probation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

~~Violations of the following codes are representative of this category:~~

~~**HEALTH AND SAFETY CODE**~~

~~11352 Importing, Selling, Furnishing Controlled Substance~~
~~11353 Adult Inducing Minor to Violate Provisions~~
~~11379 Transporting, Importing, Selling Controlled Substance~~
~~11380 Adult Using, Soliciting or Intimidating Minor for Violation~~

MODEL DISCIPLINARY LANGUAGE - ~~PHARMACIST/INTERN PHARMACIST~~ INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE, DESIGNATED REPRESENTATIVE – 3PL, ADVANCED PRACTICE PHARMACIST)

The following standardized language shall be used in every decision where the order or condition is imposed. Where brackets appear, drafters should choose the appropriate term or consider the text instructional.

Revocation

License number _____, issued to respondent _____,is revoked.

Respondent shall relinquish ~~his or her~~ [his/her] ~~wall~~ license, including any indicia of licensure issued by the board, ~~and pocket renewal license~~ to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of ~~his or her~~ [his/her] revoked license for three years from the effective date of this decision.

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.~~

~~**Option:**~~ As a condition precedent to reinstatement of ~~his or her~~ [his/her]revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of
$_____. Said amount shall be paid in full prior to the ~~reapplication or~~ reinstatement of his or her license unless otherwise ordered by the board.

Option: Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Suspension

As part of probation, respondent is suspended from ~~the~~ practice as a [insert license type] for _____[day(s)/month(s)/year(s)] ~~of pharmacy for~~ _____beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent~~

~~shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this suspension shall be considered a violation of probation.

Revocation, stayed, ~~Standard Stay/~~Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a [insert license type] license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Option: (Intern Pharmacist Only)
Should the board subsequently issue a license to practice as a pharmacist to respondent during the period of probation, the intern license shall be cancelled and the pharmacist ~~said~~ license shall be immediately revoked. The revocation of such license shall be stayed, and the probation imposed by this decision and order will continue. Respondent shall remain subject to the same terms and conditions imposed by this disciplinary order. Notwithstanding this provision, the ~~Board~~ board reserves the right to deny respondent's application for the pharmacist licensure exam. If the board issues a pharmacist license to respondent, the following additional terms and conditions shall be included as part of the disciplinary order:

Surrender

Respondent surrenders license number _____as of the effective date of this decision. Respondent shall relinquish ~~his or her~~ [his/her]~~wall~~ license, including any indicia of licensure issued by the board, ~~and/or pocket renewal license~~ to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent may only seek a new or reinstated license ~~form~~ from the board by way of a new application for licensure. Respondent ~~understands and agrees that if he or she [he/she] ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure~~ shall not be eligible to petition for reinstatement of licensure.

Respondent may not apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to, taking and passing licensing examination(s) as well as fulfilling any education or experience requirements ~~the California Pharmacist Licensure Examination~~ prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within _____days of the effective date of this decision.

Option: Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.

Public ~~Reprimand~~ Reproval

It is hereby ordered that a public ~~reprimand~~ reproval be issued against licensee, _____. Respondent is required to report this ~~reprimand~~ reproval as a disciplinary action.

License Reinstatement with Conditions Precedent (Pharmacists and Pharmacy Technicians Only)

It is hereby ordered that the petition for reinstatement is granted. Upon satisfaction of the following conditions precedent to licensure, Petitioner's License No._____ will be reinstated:

OPTION (Pharmacists Only)

a. Petitioner shall take and pass the [North American Pharmacist Licensure Examination (NAPLEX) and/or the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)/~~Pharmacy Technician Certification Board exam~~] within one (1) year of the effective date of this order. Failure to take and pass ~~both~~ the examination(s) within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement, Petitioner shall be deemed to have failed the conditions
precedent for re-licensure, and Petitioner's License No._____ shall remain [revoked or surrendered]."

b. Petitioner must pay the fee(s) in place at the time for [this/these] examinations.

c. Petitioner must pay ~~a reinstatement fee~~ all applicable application and licensing fees as well as any cost recovery owed from the prior action ~~in the amount of $~~.

Option (Pharmacy Technicians Only)

a. Petitioner shall take and pass the Pharmacy Technician Certification Board exam] within one (1) year of the effective date of this order. Failure to take and pass the examinations within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement, Petitioner shall be deemed to have failed the conditions precedent for re-licensure, and Petitioner's License No. _____ shall remain [revoked or surrendered]."

b. Petitioner must pay the fee(s) in place at the time for [this/these] examinations.

c. Petitioner must pay ~~a reinstatement fee~~ all applicable application and licensing fees as well as any cost recovery owed from the prior action ~~in the amount of $~~.

~~**Option:** Petitioner pays the Board's cost recovery or fine amount owed to the Board in the amount of $_____.~~

Upon completion of the foregoing conditions precedent, Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation for a period of _____year(s)] on the following terms and conditions.

License Reinstatement

It is hereby ordered that the petition for reinstatement filed by _____ is hereby ~~GRANTED~~ granted and Petitioner's license shall be ~~REINSTATED~~ reinstated. Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation
for a period of _____year(s)] on the following terms and conditions:

~~**Adoption of Stipulation**~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Continuing Education
6. Reporting of Employment and Notice to Employers
7. Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)

~~7.~~8. ~~No Supervision of Interns, Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant~~ Restrictions on Supervision and Oversight of Licensed Facilities

~~8~~ 9. Reimbursement of Board Costs

~~9~~ 10. Probation Monitoring Costs

~~10~~ 11. Status of License

~~11~~ 12. License Surrender While on Probation/Suspension

~~12. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

13. Certification Prior to Resuming Work

~~14. Notification of Departure~~

~~13.~~ ~~15.~~ 14. ~~Tolling of Probation~~ ~~License~~ Practice Requirement – ~~Tolling~~ Extension of Probation

~~14.~~ ~~16.~~ 15. Violation of Probation

~~15.~~ ~~17.~~ 16. Completion of Probation

OPTIONAL CONDITIONS

~~18.~~ 17. Suspension

~~16.~~ ~~19.~~ 18. Restricted Practice

~~17.~~ ~~20.~~ 19. Pharmacist Examination

~~18.~~ ~~21.~~ 20. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation

~~19.~~ ~~22.~~ 21. Psychotherapy

~~20.~~ ~~23.~~ 22. Medical Evaluation

~~21.~~ ~~24.~~ 23. Pharmacists Recovery Program (PRP)

~~22.~~ ~~25.~~ 24. ~~Random Drug Screening~~ Drug and Alcohol Testing

25. Notification of Departure

~~23.~~ 26. Abstain from Drugs and Alcohol ~~Use~~

~~24.~~ 27. Prescription Coordination and Monitoring of Prescription Use

28. Facilitated Group Recovery and/or Support Meetings

29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups

30. Work Site Monitor

~~25.~~ 31. Community Service Program

~~26.~~ 32. Restitution

~~27.~~ 33. Remedial Education

34. Ethics Course

~~28. Pharmacy Self-Assessment Mechanism (PSAM)~~

~~29. 34. Intern Pharmacist Experience~~

~~30.~~ 35. Supervised Practice

~~31. No Supervision of Ancillary Personnel~~

~~32.~~36. No Ownership or Management of Licensed Premises

~~33.~~37. Separate File of Controlled Substances Records

~~34.~~38. Report of Controlled Substances

~~35.~~39. No Access to Controlled Substances

~~36.~~40. Criminal Probation/Parole Reports

~~37. Consultant for Owner or Pharmacist-In-Charge~~

41. Tolling of Suspension

~~39.~~42. Surrender of DEA Permit
~~40.43. Ethics Course~~

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo ~~contender~~ contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- ~~discipline, citation, or other~~ the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule and in a form or format~~,~~ as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ [his/her] probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education (Pharmacists Only)

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Reporting of Employment and Notice to Employers (~~Standard 3~~)

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ~~fifteen (15)~~ ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of ~~all~~ each of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her] direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) ~~his or her~~ [his/her] direct supervisor, (b) [his/her] pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, ~~(including each new pharmacist-in-charge employed during respondent's tenure of employment)~~ and (c) the owner or owner representative of ~~his or her~~ [his/her]employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. ~~It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

If respondent works for or is employed by or through ~~a pharmacy~~ an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board~~,~~ of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity ~~his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number~~ _____~~in advance of the respondent commencing work at each licensed entity~~. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through ~~a pharmacy~~ an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above ~~his or her direct supervisor with the pharmacy~~ at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board ~~his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board~~.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision ~~shall~~ includes any full-time, part-time, temporary, relief, or employment/management service position as a [insert license type], or any position for which a [insert license type] license ~~or pharmacy management service as a pharmacist or any position for which a pharmacist license~~ is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. Notification of Change(s) in ~~Employment,~~ Name, Address(es), or Phone Number(s)[1]

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule, if known.~~ Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

~~7~~8. ~~No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant~~ Restrictions on Supervision and Oversight of Licensed Facilities[2]
(Not appropriate for Pharmacy Technicians)

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, ~~or~~ designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant ~~unless otherwise specified in this order~~. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

Option 1(To be included along with standard language when appropriate): During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians, designated representatives, designated representative-3PL in any entity licensed by the board. Assumption of any such

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[1] ~~This term was renamed and renumbered from previous term 12.~~
[2] ~~This term was renamed and consolidated with two additional terms: No Supervision of Ancillary Personnel and Consultant for Owner of Pharmacist-in-Charge.~~

unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.

Option 2 (To be used in place of standard language when appropriate): During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at ~~his/her/its~~ [his/her] expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of ~~his or her~~ [his/her] supervisory position. Respondent may serve in such a position at only one entity licensed by the board, only upon approval by the board or its designee ~~and at only one entity licensed by the board~~. ~~This~~ Any such approval shall be ~~is~~ site specific. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

~~8~~9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

~~**Option:**~~ Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~9~~10. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~10~~11. Status of License

Respondent shall, at all times while on probation, maintain an active, current [insert license type] license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current [insert license type] license shall be considered a violation of probation.

If respondent's [insert license type] license expires or is cancelled by operation of law or

otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's ~~[insert license type]~~ license shall be subject to all terms and conditions of this probation not previously satisfied.

~~11~~12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent ~~may tender [his/her] [insert license type] license to the board for~~ ~~shall~~ may relinquish [his/her] license, including any indicia of licensure issued by the board, along with a request to surrender the license ~~for surrender~~. The board or its designee shall have the discretion whether to ~~grant~~ accept the ~~request for~~ surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the ~~[insert license type]~~ license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish [his/her] pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

~~**12. Notification of a Change in Name, Residence Address, Mailing Address or Employment**~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number(s).~~

~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

13. Certification Prior to Resuming Work (Pharmacy Technicians Only)

Respondent shall be suspended, and shall not work as a pharmacy technician, until [he/she] has been certified as defined by Business and Professions Code section 4202, subdivision (a)(4), has submitted proof of certification to the board, and has been notified by the board or its designee that [he/she] may begin work. Failure to achieve certification within six (6) months of the effective date shall be considered a violation of probation. ~~Respondent shall not resume working as a pharmacy technician until notified by the board.~~

During ~~any such~~ suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs~~)~~ which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled

substances.

During ~~any such~~ this suspension, respondent shall not engage in any activity that requires licensure as a pharmacy technician. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices, or controlled substances.

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

Option: Respondent shall maintain an active, current certification as defined by Business and Professions Code section 4202, subdivision (a)(4), for the entire period of probation, and shall submit proof of re-certification or renewal of certification to the board within ten (10) days of receipt. Failure to maintain active, current certification or to timely submit proof of same shall be considered a violation of probation.

~~**14. Notification of Departure**~~

~~Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.~~

~~13.~~~~15.~~14. ~~Tolling of Probation~~ ~~License~~ Practice Requirement – ~~Tolling~~ Extension of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a ~~pharmacist~~ [insert license type] in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall ~~toll the period of probation, i.e.,~~ extend the period of probation ~~shall be extended~~ by one month ~~for each month during which this minimum is not met~~. During any such period of ~~tolling of probation~~ insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent ~~is notified otherwise~~ receives a waiver in writing ~~by~~ from the board or its designee.

~~Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____hours per calendar month in California~~, If respondent does not practice as a [insert license type] in California for ~~a~~ the minimum number of _____ hours in any calendar month, for any reason (including vacation), respondent shall ~~must~~ notify the board in writing within ten (10) days of the ~~cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice.~~ conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or ~~decline~~ reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a [insert license type] in California for ~~a~~ the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to ~~remain tolled~~ be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

~~"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.~~

~~**Option 1:** As a condition precedent to successful completion of probation, during the period of probation respondent shall practice as a [insert license type] in a licensed _____ in California that dispenses dangerous drugs and/or dangerous devices for a minimum of one (1) year. After the first year or probation, the board or its designee may consider a modification of this requirement. Failure to comply with this requirement (or as modified) shall be considered a violation of probation.~~

~~Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.~~

Option ~~2~~: ~~(First year p~~Pharmacist interns only) During respondent's ~~first academic year of~~ enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board or its designee, on [his/her] compliance with academic and vocational requirements, and on [his/her] academic progress. ~~This exemption shall apply only once, and only during respondent's first academic year.~~ Respondent must comply with all other terms and conditions of probation, unless notified in writing by the board or its designee.

~~14.~~~~16.~~15. Violation of Probation

If ~~a~~ respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~15.~~~~17.~~16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

~~18.~~17. Suspension

As part of probation, respondent is suspended from practice as a [insert license type] for _____ [day(s)/month(s)/year(s)] beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs ~~which~~ that is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with ~~any such~~ this suspension shall be considered a violation of probation.

Option ~~1~~: During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during the period of suspension shall be considered a violation of probation, and shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is notified otherwise in writing by the board or its designee.

Respondent shall notify the board or its designee in writing within ten (10) days of any departure from California, for any period, and shall further notify the board or its designee in writing within ten (10) days of return. Failure to timely provide such notification(s) shall be considered a violation of probation. Upon such departure and return, respondent shall not resume practice until notified by the board or its designee that the period of suspension has been satisfactorily completed.

~~16.~~~~19.~~18. Restricted Practice

Respondent's practice as a [insert license type] ~~of pharmacy~~ shall be restricted to [specify setting or type of practice] for the first _____year(s) of probation. Respondent shall submit proof satisfactory to the board or its designee of compliance with this term of probation.

Option: Respondent shall not prepare, oversee, or participate in the preparation of ~~injectable~~ sterile ~~products~~ compounds during the first _____year(s) of probation. Upon request, respondent ~~Respondent~~ shall submit to the board or its designee on writing, satisfactory proof ~~satisfactory~~ of compliance with this restriction, including but not limited to a written acknowledgment of this restriction signed by (a) respondent's direct supervisor, (b) the pharmacist-in-charge, and (c) the owner or owner representative of his or her employer, which explains whether the workplace in question compounds drug ~~products~~ preparations and how

this restriction will be enforced ~~term of probation~~. Failure to abide by this restriction or to timely submit proof to the board or its designee ~~of compliance therewith~~ shall be considered a violation of probation.

~~17.~~~~20.~~19. Pharmacist Examination (Pharmacists Only)

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) [and/or] the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months ~~after~~ of the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until ~~he or she~~ [he/she] takes and passes the [CPJE and/or NAPLEX] and is notified, in writing, that ~~he or she~~ [he/she] has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices and controlled susbtances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any ~~such~~ suspension shall be considered a violation of probation.

Failure to take and pass the examination(s) within ~~one (1) year~~ ~~six (6)~~ twelve (12) months of the effective date of this decision shall be considered a violation of probation.

If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. Respondent shall complete the coursework, and submit proof of completion satisfactory to the board or its designee, within three (3) months of the fourth failure of the examination. Failure to complete coursework or provide proof of such completion as required shall be considered a violation of probation.

~~18.~~20. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation (Appropriate for those cases where evidence demonstrates that ~~mental illness~~ psychiatric disorders, ~~[~~mental illness, emotional disturbance, gambling addiction), diversion, self-administration, or abuse of alcohol or drugs, or disability was a contributing cause of the violation(s).) **(~~Standards 1 & 6~~)**

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if ~~as may be~~ required by the board or its designee, respondent shall undergo, at ~~his or her~~ [his/her] own expense, ~~psychiatric~~ clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed ~~mental health~~ practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a ~~pharmacist~~ [insert license type] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.~~ If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, inpatient treatment, prescription coordination and monitoring, restricted practice), the board or
its designee may by written notice to respondent adopt ~~these~~ any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.
~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently ~~as a pharmacist~~, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board or its

designee that practice may ~~be~~ resume~~d~~.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

Option 1: (Appropriate for those cases where evidence demonstrates abuse of alcohol or drugs. Option language to be used in addition to standard language): **(~~Standards 1, 2 & 6~~)** Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [insert license type] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [insert license type];
- The board or its designee is satisfied that respondent is safe to return to practice as a [insert license type];
- Respondent receives written notice from the board or its designee that practice may resume.

For all such evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any requirement, including any suspension or deadline stated by this term shall be considered a violation of probation.

Option 2 Option language to be used in addition to standard language when deemed appropriate: Commencing on the effective date of this decision, respondent is suspended from practice and shall not ~~engage in the practice of pharmacy~~ practice as a [insert license type] until ~~notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation~~ the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice from the board or its designee that practice may resume.

The final written report of the evaluation shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices ~~and~~ or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~(Option language to be used in addition to standard language)~~

Option 3: If recommended by the ~~evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [insert license type] by providing written notice of suspension to the respondent. Upon suspension, respondent shall not resume practice as a [insert license type] until: 1) another evaluation is done at respondent's expense by a licensed practitioner selected or approved by the board or its designee; 2) the evaluator recommends that respondent return to practice; 3) the board or its designee accepts the recommendation; 4) and the board notifies the respondent in writing that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board or its designee in writing by the evaluator no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~19.~~21. Psychotherapy (Appropriate for those cases where the evidence demonstrates ~~mental illness~~ psychiatric disorders (mental illness, emotional disturbance, gambling addiction) or alcohol or drug abuse was involved in the violation(s).)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent’s own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board’s accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent’s fitness to practice, progress in treatment, and such other information ~~as may be~~ required by the

board or its designee.

If at any time the treating therapist determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or ~~and~~ controlled substances. Respondent shall not resume practice until notified by the board.

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances

~~During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with any such this suspension shall be considered a violation of probation.~~ Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~20~~.22. Medical Evaluation (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as ~~a pharmacist~~ [insert license type] with safety to the public. ~~Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.~~ If the physician recommends

restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, inpatient treatment, prescription coordination and monitoring, restricted practice), the board or its designee may by written notice to respondent adopt any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.

If the physician recommends, and the board or its designee directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics providers, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the

professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation.~~ Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(Option language to be used in addition to standard language when suspension is warranted until the evaluation is completed.)
Option 1: Commencing on the effective date of this decision, respondent shall not engage in the practice ~~of pharmacy~~ as a [insert license type] until notified in writing by the board that respondent has been deemed medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During ~~any such~~ this suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not resume practice until notified by the board.

During ~~any such~~ this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation.~~ Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~*(Option language to be used in addition to standard language)*~~
~~**Option 2:** If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing~~ pharmacy ~~as a [insert license type] until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said~~

~~recommendation. Respondent shall not resume practice until notified by the board that practice may be resumed.~~

~~During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and or devices or controlled substances. Respondent shall not resume practice until notified by the board.~~

~~During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation~~.

~~21.~~23. Pharmacists Recovery Program (PRP) (Appropriate for those cases where evidence demonstrates substance abuse ~~chemical dependency (alcohol, drugs)~~, or psychiatric disorders (mental illness, emotional disturbance, gambling addiction) (Pharmacists and Pharmacist Interns Only)

By no later than ten (10) days after ~~Within thirty (30) days of~~ the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract ~~plus~~ as well as any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). ~~contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee~~. Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP ~~and approved by the board or its designee~~. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362~~(c)~~ (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

~~Failure to timely contact or enroll in the PRP, complete the treatment contract and any addendums, complete testing registration, comply with testing, and/or successfully participate in and complete the treatment contract and/or any addendums, shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent shall not resume practice until notified in writing by the board or its designee.~~

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

- Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP;
- Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or
- Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not result the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. ~~Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~ The board will provide notice of any such suspension or extension of probation.

~~Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with any such this suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(Option language to be used in addition to standard language when appropriate to ensure licensee works in an access position while being monitored.)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing ~~probation~~ the PRP. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

~~22.~~ 24. ~~Random Drug Screening~~ Drug and Alcohol Testing (~~If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required~~ (Appropriate for those cases where the evidence demonstrates substance use.) **~~(Standards 4, 8, 9 & 10)~~**

Respondent, at ~~his or her~~ [his/her] own expense, shall participate in ~~random~~ testing~~, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program~~ as directed by the board or its designee~~. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples~~ for the detection of alcohol, ~~narcotics, hypnotics~~ controlled substances, and dangerous drugs and/or dangerous devices. ~~or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~ Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing.

Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection ~~through testing~~ of a an illicit drug, controlled substance or dangerous drug ~~and/or dangerous device~~, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug ~~and/or dangerous device~~ absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug ~~and/or dangerous device~~ absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.[3]

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent

shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~
~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

25. Notification of Departure

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

~~23.~~ ~~25.~~ 26. Abstain from Drugs and Alcohol ~~Use~~
(Appropriate for those cases where the evidence demonstrates substance use.) **(~~Standard 4~~)**

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, illicit drugs, dangerous drugs and/or dangerous devices, or ~~and~~ their associated ~~paraphernalia,~~ ~~except when~~ possessed

~~2. The Terms of Probation Designated Representative are now consolidated into "Terms of Probation – Individual Licensees."~~

or used pursuant to a legitimate prescription issued as a necessary part of treatment. ~~the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation.~~ Respondent shall ensure that ~~he or she~~ [he/she] is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs and/or dangerous devices or controlled substances, or their associated paraphernalia ~~not supported by~~ for which a legitimate prescription has not been issued as a necessary part of treatment, ~~the documentation timely provided~~, ~~and/or~~ or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

~~24.~~ ~~26.~~ 27. Prescription Coordination and Monitoring of Prescription Use (Appropriate for those cases where the evidence demonstrates substance use ~~chemical dependency (alcohol, drugs),~~ or psychiatric disorders (mental illness, emotional disturbance, gambling addiction)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, illicit drugs, controlled substances, and/or dangerous drugs ~~and/or dangerous devices~~, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. A record of this notification must be provided to the

board or its designee upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing ~~treatment~~ supervision, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the ~~required reporting thereby on the quarterly reports~~ required quarterly reporting thereby, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a [insert license type] until notified by the board or its designee that practice may be resumed.

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type] ~~of a pharmacist~~. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with any such this suspension shall be considered a violation of probation~~. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

~~39.~~28. Facilitated Group Recovery and/or Support Meetings (Appropriate for those cases where the evidence demonstrates substance use. Pharmacists and Pharmacist Interns Only) **(~~Standard 5~~)**

Within thirty (30) days of the effective date of this decision, respondent shall begin regular

attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises the respondent in writing that [he/she] may cease regular attendance.

Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as required in a facilitated group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

~~40.~~29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
(Appropriate for those cases where the evidence demonstrates substance use.)
(~~Standard 5~~)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend ~~at least one~~ the number of group meetings per week or month ~~unless otherwise~~ directed by the board or its designee, which shall typically be at least one per week. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

~~If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program.~~ Where respondent is enrolled in the PRP, participation as required in a recovery group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

~~41.~~30. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance use.)[4] **(~~Standard 7~~)**

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

~~The initial~~ In the event of suspected abuse, the monitor shall make at least oral notification ~~shall be made orally~~ within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

[4] ~~This probationary term is not new, but is being moved from the previous section "Pharmacy Technician – Standard Terms and Conditions" for purposes of consolidation. The language of this term is also changing from the previous version.~~

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the board to allow the board or its designee to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Option (Alternate language that is appropriate for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, ~~and~~ which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

~~25.~~~~27.~~31. Community Service~~s~~ Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free [insert type of service, e.g., health-care related services] on a regular basis to a community or charitable facility or agency for at least _____hours per _____for the first _____of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board or its designee demonstrating commencement of the community service program. ~~A record of this notification must be provided to the board upon request.~~ Respondent shall report on progress with the community service program in the quarterly reports and provide satisfactory documentary evidence of such progress to the board or its designee upon request. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~26.~~~~28.~~32. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____days of the effective date of this decision, respondent shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~27.~~~~29.~~33. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____hours, which shall be completed within _____months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at ~~his or her~~ [his/her] own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination~~, this failure shall be considered a violation of probation. Any such examination failure shall require~~ that course shall not count towards satisfaction of this term. ~~r~~Respondent ~~to~~ shall take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

~~40.~~~~38.~~34. Ethics Course (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only)

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a

course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully ~~and~~ complete it before the end of ~~within~~ the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered ~~is~~ a violation of probation.

~~Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.~~

~~28. Pharmacy Self-Assessment Mechanism~~

~~Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.~~

~~Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.~~

~~**Option A:** Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.~~

~~**Option B:** (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education~~.

~~29. 30. Intern Pharmacist Experience (Intern Pharmacist Only)~~

~~Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a pharmacy intern training program consisting of _____ hours to be served as an intern pharmacist in a community and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall, by no later than one (1) year and ten (10) days from the effective date of this decision, submit proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.~~

30. ~~31.~~35. Supervised Practice (~~This term is not appropriate~~ See Option for Pharmacy Technicians.)

~~During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his or her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:~~ Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall

cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by a respondent and shall be considered a violation of probation:

- Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;
- Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;
- Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or
- Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

~~Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be automatically suspended from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing..~~

~~Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of~~

~~probation.~~

~~If respondent changes employment, it shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~Within ten (10) days of leaving employment, respondent shall notify the board in writing.~~

During any ~~such~~ suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any ~~such~~ suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type]~~of a pharmacist~~. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any ~~such~~ suspension shall be considered a violation of probation.

Option: (For Pharmacy Technicians Only)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that her or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. Respondent may have multiple supervisors approved by the board if necessary to meet respondent's work requirements.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or

its designee. If any of these obligations or prohibitions is not met, respondent shall be prohibited from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing.

~~31. No Supervision of Ancillary Personnel~~[2]

~~During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.~~

~~Failure to comply with this provision shall be considered a violation of probation.~~

~~32.~~36. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, ~~or~~ nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option (To be used in place of the standard language in those circumstances where respondent is permitted to continue existing ownership of a licensed entity): Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

~~33.~~37. Separate File of Controlled Substances Records (~~For pharmacist~~ Pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~34.~~38. Report of Controlled Substances (~~For pharmacist~~ Pharmacist owners and pharmacists-in-charge)

Respondent shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~35.~~39. No Access to Controlled Substances

During the period of probation and as directed by the board or its designee, respondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedules I, II, III, IV or V (Health and Safety Code sections ~~11055~~ 11054 -11058 inclusive). Respondent shall not order, receive or retain any security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

~~36.~~40. Criminal Probation/Parole Reports

~~Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of his or her [his/her] probation/parole officer to the board, in writing, within ten (10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.~~

Within ten (10) days of the effective date of this decision, or within ten (10) days of the issuance or assignment/replacement of same, whichever is earlier, respondent shall provide the board or its designee in writing: a copy of the conditions of any criminal probation/parole applicable to respondent; and the name and contact information of any probation, parole or similar supervisory officer assigned to respondent. On an following the effective date, respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after such report is issued. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

~~37. Consultant for Owner or Pharmacist-In-Charge~~

~~(Option #1 for pharmacist owners - primarily intended for appropriate cases where the respondent is the sole owner and pharmacist-in-charge of his or her own pharmacy, the standard language should be used in most cases.)~~

~~During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

~~(Option #2 - appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided documented mitigating evidence to warrant this option.)~~

~~During the period of probation, respondent shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the~~

~~obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval. Within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

~~38. Tolling of Suspension~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.~~

~~39~~ ~~37.~~ 42. Surrender of DEA Permit (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only)

Within thirty (30) days of the effective date of this decision, respondent shall surrender ~~his or her~~ [his/her] federal Drug Enforcement Administration (DEA) permit to the DEA~~,~~ for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from ~~prescribing~~ dispensing, furnishing, or otherwise providing dangerous drugs and/or dangerous devices or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option 1: Respondent may obtain a DEA permit restricted to Schedule(s) _____controlled substance(s).

Option 2: Respondent shall not order, receive, or retain any federal order forms, including DEA form 222 forms, for controlled substances.

~~PHARMACY TECHNICIAN~~

~~The board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to the following violation(s) of law(s) involving:~~

- ~~Possession of dangerous drugs and/or controlled substances~~
- ~~Use of dangerous drugs and/or controlled substances~~
- ~~Possession for sale of dangerous drugs and/or controlled substances~~
- ~~Personal misuse of drugs or alcohol~~

~~If revocation is not imposed, the board recommends a minimum Category III level of discipline~~

~~be imposed on the pharmacy technician. This would include suspension and probation.~~

~~In addition, a pharmacy technician would be required to obtain certification as defined by Business and Professions Code section 4202(a)(4) prior to resuming work as a pharmacy technician. The board believes that certification prior to resuming work is always warranted in cases where a pharmacy technician license is disciplined but not revoked.~~

~~Pharmacy technicians are issued a license based on minimal education, training requirements or certification. No examination is required for issuance of the registration. Pharmacy technicians are not independent practitioners and must work under the supervision of a pharmacist. To place a pharmacy technician on probation places an additional burden on the pharmacist (who may or may not be on probation) to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation.~~

~~TERMS OF PROBATION – PHARMACY TECHNICIAN~~[4]

~~A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.~~

~~Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).~~

~~The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.~~

~~**CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES**~~

~~**CATEGORY III - Penalty**~~

~~Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.~~

~~Maximum: Revocation~~

~~Applies to all applicable statutes and regulations~~

~~**MODEL DISCIPLINARY LANGUAGE – PHARMACY TECHNICIAN**~~[5]

~~The following standardized language shall be used in every decision where the order of condition is imposed.~~

~~**Revocation**~~

~~Pharmacy technician license number _____, issued to respondent _____is revoked. Respondent shall relinquish his or her technician license to the board within ten (10) days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked technician license for three (3) years from the effective date of this decision.~~

~~A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board.~~

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____within fifteen (15) days of the effective date of this decision.~~

~~**Option:** As a condition precedent to reinstatement of his or her revoked technician license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her revoked technician license, unless otherwise ordered by the board.~~

~~**Suspension**~~

~~As part of probation, respondent is suspended from working as a pharmacy technician for _____beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have~~

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[5] ~~All information specific to Pharmacy Technician is being removed and consolidated into Terms of Probation – Individual Licensees.~~

~~access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~Standard Stay/Probation Order~~

~~Pharmacy technician license number _____is revoked; however the revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~Issuance of Probationary License~~ ~~(In cases where a Statement of Issues has been filed.)~~

~~Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~Surrender~~

~~Respondent surrenders pharmacy technician license number _____as of the effective date of this decision. Respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of the effective date of this decision.~~

~~The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.~~

~~Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.~~

~~Respondent may not apply for any license, permit, or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to certification by a nationally recognized body prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.~~

~~Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_ _____within _____days of the effective date of this decision.~~

~~**Option:** Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the license.~~

~~**Public Reprimand**~~

~~It is hereby ordered that a public reprimand be issued against pharmacy technician license, _____. Respondent is required to report this reprimand as a disciplinary action.~~

~~**Adoption of Stipulation**~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

~~**STANDARD CONDITIONS** – To be included in all probation decisions/orders.~~

1. ~~Certification Prior to Resuming Work~~
2. ~~Obey All Laws~~
3. ~~Report to the Board~~
4. ~~Interview with the Board~~
5. ~~Cooperate with Board Staff~~
6. ~~Notice to Employers~~
7. ~~Reimbursement of Board Costs~~
8. ~~Probation Monitoring Costs~~
9. ~~Status of License~~
10. ~~License Surrender While on Probation/Suspension~~
11. ~~Notification of a Change in Name, Residence Address, Mailing Address or Employment~~
12. ~~Tolling of Probation~~
13. ~~Violation of Probation~~
14. ~~Completion of Probation~~

~~**OPTIONAL CONDITIONS**~~

15. ~~No Ownership of Licensed Premises~~
16. ~~Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~
17. ~~Random Drug Screening~~
18. ~~Work Site Monitor~~
19. ~~Notification of Departure~~
20. ~~Abstain from Drugs and Alcohol Use~~
21. ~~Tolling of Suspension~~
22. ~~Restitution~~

~~STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS~~

~~1. Certification Prior to Resuming Work~~

~~Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified as defined by Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~2. Obey All Laws~~

~~Respondent shall obey all state and federal laws and regulations.~~

~~Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:~~

- ~~an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws~~
- ~~a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment~~
- ~~a conviction of any crime~~
- ~~discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.~~

~~Failure to timely report any such occurrence shall be considered a violation of probation.~~

~~3. Report to the Board~~

~~Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports~~

~~in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.~~

~~4. Interview with the Board~~

~~Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.~~

~~5. Cooperate with Board Staff~~

~~Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.~~

~~6. Notice to Employers~~

~~During the period of probation, respondent shall notify all present and prospective employers of the decision in case number~~ _____ ~~and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~

~~Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number~~ _____ ~~and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.~~

~~If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of the decision in case number~~ _____ ~~in advance of the respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.~~

~~Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number~~ _____ ~~and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

~~Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee, independent contractor or volunteer.~~

~~7. Reimbursement of Board Costs~~

~~As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~8. Probation Monitoring Costs~~

~~Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~9. Status of License~~

~~Respondent shall, at all times while on probation, maintain an active, current pharmacy technician license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.~~

~~If respondent's pharmacy technician license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.~~

~~10. License Surrender While on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her pharmacy technician license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all~~

~~requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

~~11. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.~~

~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

~~12. Tolling of Probation~~

~~Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Should respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of _____hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of the work. Any failure to provide such notification(s) shall be considered a violation of probation.~~

~~It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.~~

> ~~"Cessation of work" means calendar month during which respondent is not working for at least _____hours as a pharmacy technician, as defined in Business and Professions Code section 4115. "Resumption of work" means any calendar month during which respondent is working as a pharmacy technician for at least _____hours as a pharmacy technician as defined by Business and Professions Code section 4115.~~

~~13. Violation of Probation~~

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.~~

~~If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a~~

~~violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.~~

~~14. Completion of Probation~~

~~Upon written notice by the board indicating successful completion of probation, respondent's pharmacy technician license will be fully restored.~~

~~OPTIONAL CONDITIONS OF PROBATION~~

~~15. No Ownership of Licensed Premises~~

~~Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.~~

~~Option:~~ ~~Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision. Violation of this restriction shall be considered a violation of probation.~~

~~16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~ ~~(Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.~~

~~17. Random Drug Screening~~ ~~(Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be~~

~~determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of work by respondent. Respondent may not resume work as a pharmacy technician until notified by the board in writing.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.~~

~~Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~**18. Work Site Monitor** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.~~

~~**19. Notification of Departure** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.~~

~~**20. Abstain from Drugs and Alcohol Use** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.~~

~~**21. Tolling of Suspension**~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not return to work until notified by the board that the period of suspension has been satisfactorily completed.~~

~~**22. Restitution** (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)~~

~~Within _____days of the effective date of this decision, respondent shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.~~

~~DESIGNATED REPRESENTATIVE~~

~~The board files cases against designated representatives where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to, the following violation(s) of law(s) involving:~~

- ~~Possession of dangerous drugs and/or controlled substances~~
- ~~Use of dangerous drugs and/or controlled substances~~
- ~~Possession for sale of dangerous drugs and/or controlled substances~~
- ~~Personal misuse of drugs or alcohol~~

~~If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the designated representative. This would include suspension and probation.~~

~~TERMS OF PROBATION – DESIGNATED REPRESENTATIVE~~[6]

~~A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.~~

~~Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).~~

~~The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.~~

~~CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES~~

~~CATEGORY III - Penalty~~

~~Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.~~

~~Maximum: Revocation~~

~~Applies to all applicable statutes and regulations~~

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[6] ~~All information specific to Designated Representative is being removed and consolidated into Terms of Probation – Individual Licensees.~~

~~MODEL DISCIPLINARY LANGUAGE – DESIGNATED REPRESENTATIVE~~

~~The following standardized language shall be used in every decision where the order of condition is imposed.~~

~~Revocation~~

~~Designated Representative license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked designated representative license for three (3) years from the effective date of this decision.~~

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____within fifteen (15) days of the effective date of this decision.~~

~~Option:~~ ~~As a condition precedent to reinstatement of his or her revoked designated representative license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reinstatement of his or her revoked designated representative license, unless otherwise ordered by the board.~~

~~Suspension~~

~~As part of probation, respondent is suspended from working as a designated representative for _____beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.~~

~~Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~Standard Stay/Probation Order~~

~~Designated representative license number _____is revoked; however, the revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~**Issuance of Probationary License** (In cases where a Statement of Issues has been filed.)~~

~~Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years upon the following terms and conditions:~~

~~**Surrender**~~

~~Respondent surrenders designated representative license number _____as of the effective date of this decision. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision.~~

~~The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.~~

~~Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.~~

~~Respondent may not apply for any license, permit or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board prior to issuance of a new license. Respondent is required to report this surrender as disciplinary action.~~

~~Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within _____days of the effective date of this decision.~~

~~**Option:** Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.~~

~~**Public Reprimand**~~

~~It is hereby ordered that a public reprimand be issued against designated representative license, _____. Respondent is required to report this reprimand as a disciplinary action.~~

~~**Adoption of Stipulation**~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

~~**STANDARD CONDITIONS** – To be included in all probation decisions/orders.~~

1. ~~Obey All Laws~~
2. ~~Report to the Board~~
3. ~~Interview with the Board~~
4. ~~Cooperate with Board Staff~~
5. ~~Notice to Employers~~
6. ~~No Being Designated Representative-in-Charge~~
7. ~~Reimbursement of Board Costs~~
8. ~~Probation Monitoring Costs~~
9. ~~Status of License~~
10. ~~License Surrender While on Probation/Suspension~~
11. ~~Notification of a Change in Name, Residence Address, Mailing Address or Employment~~
12. ~~Tolling of Probation~~
13. ~~Violation of Probation~~
14. ~~Completion of Probation~~

~~**OPTIONAL CONDITIONS**~~

15. ~~No Ownership of Licensed Premises~~
16. ~~Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~
17. ~~Random Drug Screening~~
18. ~~Work Site Monitor~~
19. ~~Notification of Departure~~
20. ~~Abstain from Drugs and Alcohol Use~~
21. ~~Tolling of Suspension~~
22. ~~Restitution~~

~~STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS~~

~~1. Obey All Laws~~

~~Respondent shall obey all state and federal laws and regulations.~~

~~Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:~~

- ~~an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws~~
- ~~an arrest or issuance of a criminal complaint for violation of any state or federal law~~
- ~~a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment~~
- ~~a conviction of any crime~~
- ~~discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.~~

~~Failure to timely report any such occurrence shall be considered a violation of probation.~~

~~2. Report to the Board~~

~~Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.~~

~~3. Interview with the Board~~

~~Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, upon request at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.~~

~~4. Cooperate with Board Staff~~

~~Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.~~

~~5. Notice to Employers~~

~~During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____and the terms, conditions and restrictions imposed on respondent by the decision, as follows:~~

~~Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.~~

~~If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, designated representative-in-charge and owner at each entity licensed by the board of the terms and conditions of the decision in case number _____in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.~~

~~Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

~~Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.~~

> ~~"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.~~

~~6. No Being Designated Representative-in-Charge~~

~~During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.~~

~~7. Reimbursement of Board Costs~~

~~As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~8. Probation Monitoring Costs~~

~~Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.~~

~~9. Status of License~~

~~Respondent shall, at all times while on probation, maintain an active, current designated representative license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.~~

~~If respondent's designated representative license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.~~

~~10. License Surrender While on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her designated representative license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her designated representative license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

~~11. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.~~
~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

~~12. Tolling of Probation~~

~~Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of _____hours in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.~~

~~It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.~~

> ~~"Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least _____hours as a designated representative as defined by Business and Professions Code section 4053.~~
> ~~"Resumption of work" means any calendar month during which respondent is working as a designated representative for at least _____hours as a designated representative as defined by Business and Professions Code section 4053.~~

~~13. Violation of Probation~~

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.~~

~~If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.~~

~~14. Completion of Probation~~

~~Upon written notice by the board indicating successful completion of probation, respondent's designated representative license will be fully restored.~~

~~**OPTIONAL CONDITIONS OF PROBATION**~~

~~**15. No Ownership of Licensed Premises**~~

~~Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.~~

~~**Option:** Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.~~

~~**16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.~~

~~**17. Random Drug Screening** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result~~

~~in the automatic suspension of work by respondent. Respondent may not resume work as a designated representative until notified by the board in writing.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.~~

~~Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~**18. Work Site Monitor** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.~~

~~**19. Notification of Departure** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.~~

~~**20. Abstain from Drugs and Alcohol Use** (Appropriate for those cases with chemical dependency (alcohol, drugs))~~

~~Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of~~

~~the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.~~

~~21. Tolling of Suspension~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume work until notified by the board that the period of suspension has been satisfactorily completed.~~

~~22. Restitution~~ ~~(Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)~~

~~Within~~ _____ ~~days of the effective date of this decision, respondent shall pay restitution to~~ _____ ~~in the amount of $~~ _____. ~~Failure to make restitution by this deadline shall be considered a violation of probation.~~

TERMS OF PROBATION – PREMISES

A ~~minimum~~ three-year probation period has been established by the board as the minimum appropriate length in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of dangerous drugs or devices or controlled substances has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against a license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.~~

For those licenses issued to premises the board has identified four (4) categories of violations and associated recommended minimum and maximum penalties for each. These categories of violations are arranged in ascending order from the ~~less~~ least serious (Category I) to the most serious (Category IV), although any violation in any category, or any combination of violation(s) in one or more categories, may merit revocation.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive.~~ For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation ~~of each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if a~~n~~ ~~individual~~ respondent has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; ~~one~~ two years probation. All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are less serious than Categories II through IV but are potentially harmful:

- violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff to ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of packaging requirements, security control requirements, or reporting requirements; and
- failure(s) to display original license(s), or to supply name(s) of owner(s), manager(s), or employee(s).
- violation(s) involving the improper compounding of drug products
- ~~violations which are relatively minor but are potentially harmful~~
- ~~repeated violations of a relatively minor nature~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4053 Exemptee Supervisor of Manufacturer, etc.: Requirements~~
~~4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices~~
~~4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less~~
~~4057 Exceptions to Application of this Chapter~~
~~4058 Display of Original License~~
~~4062 Furnishing Dangerous Drugs During Emergency~~
~~4064 Emergency Refill of Prescription Without Prescriber Authorization~~
~~4065 Injection Card System; Requirements for Administration~~
~~4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel~~

~~Article 4. Requirements for Prescription~~

~~4070 Reduction of Oral or Electronic Prescription to Writing~~
~~4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded~~
~~4072 Oral or Electronic Transmission of Prescription - Health Care Facility~~
~~4073 Substitution of Generic Drug - Requirements and Exceptions~~
~~4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications~~
~~4076 Prescription Container - Requirements for Labeling~~
~~4077 Dispensing Dangerous Drug in Incorrectly Labeled Container~~

~~Article 5. Authority of Inspectors~~

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

~~Article 6. General Requirements~~

~~4100 Change of Address or Name – Notification to Board~~
~~4103 Blood Pressure - Taking by Pharmacist~~

~~Article 7. Pharmacies~~

~~4114 Intern Pharmacist: Activities Permitted~~
~~4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4121 Advertisement for Prescription Drug: Requirements; Restrictions~~
~~4122 Required Notice at 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~~

~~Article 9. Hypodermic Needles and Syringes~~

~~4141 Furnishing Without License~~
~~4142 Prescription Required~~
~~4143 Exemption: Sale to Other Entity, Physician, etc.~~
~~4144 Industrial Use Exception~~
~~4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions~~
~~4148 Confiscation if Found Outside Licensed Premises~~
~~4149 Sale by Distributor~~

~~Article 10. Pharmacy Corporations~~

~~4151 Licensure Requirements~~
~~4152 Corporate Name Requirements~~
~~4153 Shareholder Income While Disqualified~~
~~4156 Unprofessional Conduct by Corporation~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~

~~4162 Issuance or Renewal of Wholesaler License; Surety Bond~~
~~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~~
~~4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises~~

~~Article 13. Non-Profit or Free Clinics~~

~~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 Prohibited~~
~~4186 Automated Drug Delivery Systems~~

~~Article 14. Surgical Clinics~~

~~4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required~~
~~4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs~~
~~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~~

~~Article 15. Veterinary Food-Animal Drug Retailers~~

~~4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area~~
~~4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers~~
~~4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist~~

~~Article 17. Continuing Education~~

~~4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee~~
~~4232 Content of Courses~~

~~Article 18. Poisons~~

~~4240 Application of Act~~

~~Article 20. Prohibitions and Offenses~~

~~4341 Advertisement of Prescription Drugs or Devices~~
~~4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1704 Change of Address~~
~~1705 Notification of Bankruptcy, Receivership or Liquidation~~
~~1708.2 Discontinuance of Business~~
~~1708.4 Pharmacist Handling Radioactive Drugs~~
~~1708.5 Pharmacy Furnishing Radioactive Drugs~~
~~1709 Names of Owners and Pharmacist in Charge~~
~~1714 Operational Standards and Security~~
~~1715.6 Reporting Drug Loss~~
~~1716 Variation from Prescriptions~~
~~1717 Pharmaceutical Practice~~
~~1717.1 Common Electronic Files~~
~~1717.4 Electronic Transmission of Prescriptions~~
~~1718.1 Manufacturer's Expiration Date~~
~~1726 Supervision of Intern Pharmacists~~
~~1728 Requirements for Examination~~
~~1732.1 Requirements for Accredited Providers~~
~~1732.3 Requirements for Continuing Education Courses~~
~~1732.4 Provider Audit Requirements~~
~~1732.5 Renewal Requirements for Pharmacist~~
~~1744 Drug Warnings~~
~~1751 Sterile Injectable Compounding Area~~
~~1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients~~
~~1751.02 Policies and Procedures~~
~~1751.11 Furnishing to Home Health Agencies and Licensed Hospices~~
~~1751.12 Obligations of a Pharmacy Furnishing Portable Containers~~
~~1771 Posting of Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1780 Minimum Standards for Wholesalers~~
~~1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers~~
~~1781 Exemption Certificate~~
~~1786 Exemptions~~
~~1787 Authorization to Distribute Hemodialysis Drugs and Devices~~
~~1790 Assembling and Packaging~~
~~1791 Labeling~~
~~1792 Receipt for Shipment~~

~~HEALTH AND SAFETY CODE~~

~~11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties~~
~~11100.1 Report of Chemicals Received from Outside State; Penalties~~
~~11151 Limitation on Filling Prescriptions From Medical Students~~
~~11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration~~
~~11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years~~

~~11159.1 Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years~~
~~11159.2 Exception to Triplicate Prescription Requirement~~
~~11167 Emergency Dispensing of Schedule II Substance: Circumstances and Requirements~~
~~11167.5 Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements~~
~~11171 Prescribing, etc. Controlled Substance Only as Authorized~~
~~11172 Antedating or Postdating Prescription Prohibited~~
~~11175 Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription~~
~~11180 Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription~~
~~11200 Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred~~
~~11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements~~
~~11205 Maintenance and Retention of Records in Separate File~~
~~11206 Required Information on Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed~~
~~11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form~~
~~11251 Authorized Wholesale Sale by Pharmacists~~
~~11252 Preservation of Federally Required Forms~~
~~11253 Duration of Retention~~
~~11255 Actions Constituting Sale~~
~~11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer~~
~~111225 to~~
~~111655 Adulterated or Misbranded Drugs or Devices~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.~~
~~1301.14 Filing of application; acceptance for filing; defective applications.~~
~~1301.71 Security requirements generally.~~
~~1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.~~
~~1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.~~
~~1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.~~
~~1301.77 Security controls for freight forwarding facilities.~~
~~1301.90 Employee screening procedures.~~
~~1301.91 Employee responsibility to report drug diversion.~~
~~1301.92 Illicit activities by employees.~~
~~1302.03 Symbol required; exceptions.~~
~~1302.04 Location and size of symbol on label and labeling.~~
~~1302.05 Effective dates of labeling requirements.~~
~~1302.06 Sealing of controlled substances.~~
~~1302.07 Labeling and packaging requirements for imported and exported substances.~~

~~1304.11 Inventory requirements.~~
~~1304.31 Reports from manufacturers importing narcotic raw material.~~
~~1304.32 Reports of manufacturers importing coca leaves.~~
~~1304.33 Reports to ARCOS.~~
~~1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.~~
~~1305.04 Persons entitled to order Schedule I and II controlled substances.~~
~~1305.05 Power of attorney.~~
~~1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.~~
~~1305.11 Procedure for obtaining DEA Forms 222.~~
~~1305.12 Procedure for executing DEA Forms 222.~~
~~1305.14 Procedure for endorsing DEA Forms 222.~~
~~1305.15 Unaccepted and defective DEA Forms 222.~~
~~1305.16 Lost and stolen DEA Forms 222.~~
~~1306.03 Persons entitled to issue prescriptions.~~
~~1306.05 Manner of issuance of prescriptions.~~
~~1306.14 Labeling of substances and filling of prescriptions.~~
~~1306.24 Labeling of substances and filing of prescriptions.~~
~~1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.~~
~~1306.26 Dispensing without a prescription.~~
~~1307.11 Distribution by dispenser to another practitioner or reverse distributor.~~
~~1307.12 Distribution to supplier or manufacturer.~~
~~1307.13 Incidental manufacture of controlled substances.~~
~~1307.21 Procedure for disposing of controlled substances.~~
~~1700.1 to~~
~~1707.15 Child-resistant containers.~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of dangerous drugs and/or dangerous devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competency, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;

- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of laws governing dangerous drugs and/or dangerous devices and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drugs and/or dangerous devices via the internet, without a valid prescription;
- purchasing, trading, selling, or transferring dangerous drugs and/or dangerous devices to or from unauthorized person(s);
- failure(s) to make required reports to the board or to other regulatory agencies, including CURES obligations and reporting to the DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- failure~~(s)~~ to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs or devices or controlled substances;
- repeat or serious deviation(s) from the requirements of prescription(s) or failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonestly, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous devices or controlled substances;
- violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- repeat or serious violation(s) involving the improper compounding of drug products

- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

~~Violations of the following codes are representative of this category:~~

~~BUSINESS AND PROFESSIONS CODE~~

~~650 Rebates or Discounts for Referral Prohibited~~
~~650.1 Lease Prohibition – Hospitals or Prescribers~~
~~651 Professional Advertising Requirements~~

~~Article 3. Scope of Practice and Exemptions~~

~~4051(b) Conduct Authorized by Pharmacist~~
~~4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care~~

~~Facility or Clinic or for Other Health Care Provider~~
~~4060 Controlled Substance – Prescription Required; Exceptions~~
~~4061 Distribution of Drug as Sample; Written Request Required~~
~~4064 Emergency Refill of Prescription Without Prescriber Authorization~~
~~4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription~~
~~4075 Proof of Identity Required – Oral or Electronic Prescription~~
~~4078 False or Misleading Label on Prescription~~

~~Article 6. General Requirements~~

~~4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board~~
~~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~~

~~Article 7. Pharmacies~~

~~4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation~~
~~4113 Pharmacist in Charge: Notification to Board; Responsibilities~~
~~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~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents~~

~~Article 9. Hypodermic Needle and Syringes~~

~~4140 Unlawful Possession~~
~~4147 Disposal of Needle or Syringe~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~
~~4163 Unauthorized Furnishing by Manufacturer or Wholesale~~
~~4164 Reports Required~~
~~4169(a)(1) Prohibited Acts~~

~~Article 13. Non-Profit of Free Clinics~~

~~4185 Inspection Permitted~~

~~Article 14. Surgical Clinics~~

~~4195 Inspection Permitted~~

~~Article 19. Disciplinary Proceedings~~

~~4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l) - (q)~~

~~4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder~~
~~4303 Nonresident Pharmacy: Grounds for Discipline~~
~~4304 Out-of-state Distributor: Authority to Discipline~~
~~4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist~~
~~4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee~~
~~4306 Violation of Professional Corporation Act as Unprofessional Conduct~~
~~4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct~~

~~Article 20. Prohibitions and Offenses~~

~~4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another~~
~~4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist~~
~~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 Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee~~
~~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 as Misdemeanor~~
~~4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs; Prohibition; Exceptions~~
~~4382 Board May Audit Sales to Walk-in Customers~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)~~
~~1707.2 Notice to Consumers and Duty to Consult~~
~~1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver~~
~~1709.1 Designation of Pharmacist in Charge~~
~~1714.1 Pharmacy Operation During Temporary Absence of a Pharmacist~~
~~1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge~~
~~1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions~~
~~1716.1 Compounding Unapproved Drugs for Prescriber Office Use~~
~~1716.2 Record Requirements-Compounding for Future Furnishing~~
~~1717.2 Notice of Electronic Prescription Files~~
~~1717.3 Preprinted, Multiple Checkoff Prescription Blanks~~
~~1723.1 Confidentiality of Examination Questions~~
~~1745 Partial Filling of Schedule II Prescriptions~~
~~1751.10 Furnishing to Parenteral Patient at Home~~

~~1761(a) Erroneous or Uncertain Prescriptions~~
~~1764 Unauthorized Disclosure of Prescriptions~~
~~1765 Commissions, Gratuities, and Rebates~~
~~1766 False or Misleading Advertising~~
~~1775.3 Compliance with Orders of Abatement~~
~~1782 Reporting Sales of Drugs Subject to Abuse~~
~~1783 Manufacturer or Wholesaler Furnishing Drugs or Devices~~
~~1793.1 Duties of a Pharmacist~~
~~1793.2 Duties of a Pharmacy Technician~~
~~1793.3 Other Non-Licensed Pharmacy Personnel~~
~~1793.4 Qualifications for Registration as a Pharmacy Technician~~
~~1793.7 Requirements for Pharmacies Employing Pharmacy Technicians~~
~~1793.8 Technicians in Hospitals with Clinical Pharmacy Programs~~

~~HEALTH AND SAFETY CODE~~

~~11103 Report of Theft, Loss, or Shipping Discrepancy~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11152 Nonconforming Prescriptions Prohibited~~
~~11154 Prescription, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.~~
~~11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized~~
~~11164 Prescriptions for Schedule II, III, IV and V Controlled Substance: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance~~
~~11165(d) CURES Transmission~~
~~11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited~~
~~11170 Prohibition on Prescribing, etc. Controlled Substance for Self~~
~~11179 Retention of Controlled Substance Prescription~~
~~11207 Only Pharmacist or Intern Authorized to Fill Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11350 Possession of Specified Controlled Substance~~
~~11377 Unlawful Possession of Specified Substance~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1304.03 Persons required to keep records and file reports.~~
~~1304.04 Maintenance of records and inventories.~~
~~1304.11 Inventory requirements.~~
~~1304.21 General requirements for continuing records.~~
~~1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.~~
~~1305.07 Special procedures for filling certain orders.~~
~~1305.13 Procedure for filling DEA Forms 222.~~
~~1306.04 Purpose of issue of prescription.~~
~~1306.06 Persons entitled to fill prescriptions.~~
~~1306.11 Requirement prescription.~~
~~1306.12 Refilling prescriptions.~~

~~1306.13 Partial filling of prescriptions.~~
~~1306.21 Requirement of prescription.~~
~~1306.22 Refilling of prescriptions.~~
~~1306.23 Partial filling of prescriptions.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of dangerous drugs and/or dangerous devices or controlled substances, or abusive use of alcohol, occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by electronic pedigree requirements for dangerous drugs;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;
- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices,
  controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) and/or dangerous devise(s) or controlled substances
- resale(s) of preferentially prices drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) and/or dangerous device(s) or controlled substances(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to

violate the laws and regulations governing pharmacy; and

- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
- repeat or serious violation(s) involving the improper compounding of drug products
- ~~most criminal convictions involving dangerous drugs or controlled substances~~
- ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
- ~~fraudulent acts committed in connection with the licensee's practice~~
- ~~drug shortages~~
- ~~violation of a licensee's corresponding responsibility.~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4051(a) Conduct Limited to Pharmacist~~
~~4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions~~
~~4059.5 Who May Order Dangerous Drugs or Devices: Exceptions~~

~~**Article 5. Authority of Inspectors**~~

~~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~~
~~4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device~~

~~**Article 7. Pharmacies**~~

~~4110 License Required; Temporary Permit Upon Transfer of Ownership~~
~~4111 Restrictions on Prescriber Ownership~~

~~**Article 11. Wholesalers and Manufacturers**~~

~~4169(a)(2) to~~
~~4169(a)(5) Prohibited Acts~~

~~**Article 15. Veterinary Food-Animal Retailers**~~

~~4199 Labeling Requirements; Maintaining Prescription Records~~

~~**Article 19. Disciplinary Proceedings**~~

~~4301 Unprofessional Conduct - subsections (i) - (k) and (o)~~
~~4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding~~
~~4308 Prohibited Association: Notification of Affected Licensees Known to Board~~

~~Article 20. Prohibitions and Offenses~~

~~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~~
~~4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages~~
~~4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs~~
~~4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records~~
~~4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor~~
~~4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1718 Current Inventory Defined~~
~~1761(b) Erroneous or Uncertain Prescriptions~~
~~1771 Posting of Notice of Suspension~~
~~1772 Disciplinary Condition of Suspension~~
~~1773 Disciplinary Conditions of Probation of Pharmacist~~
~~1774 Disciplinary Conditions of Probation of Permit~~

~~HEALTH AND SAFETY CODE~~

~~11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~
~~11105 False Statement in Report~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist~~
~~11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy~~
~~11157 No False or Fictitious Prescriptions~~
~~11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty~~
~~11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled Nursing Facility~~
~~11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label~~

~~11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.~~
~~11351 Possession or Purchase for Sale of Specified Controlled Substance~~
~~11368 Forged or Altered Prescriptions~~
~~11375 Possession for Sale or Selling Specified Substance~~
~~11378 Possession for Sale~~
~~11550 Using or Being Under Influence of Controlled Substance~~
~~111295 Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device~~
~~111300 Unlawful to Adulterate a Drug~~
~~111305 Unlawful to Receive in Commerce an Adulterated Drug~~
~~111440 Unlawful Manufacturer, selling a misbranded Drug~~
~~111445 Unlawful for a Person to Misbrand~~
~~111450 Unlawful to Receive into Commerce a Drug that is Misbranded~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (~~Revocation~~ revocation) is recommended for the most serious violations of ~~the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving~~ laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:

- violation(s) involving possession for sale, transportation, importation, and/or use of a minor for unlawful acquisition of sale, of controlled substances;
- criminal conviction(s) involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices, or controlled substances; and
- repeat or serious example(s) of conduct described in Category I, Category II, or Category III.
- ~~possession for sale~~
- ~~transportation~~
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when~~ where a respondent fails to file a notice of defense to a pleading requiring a timely notice of defense or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.~~:~~

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

~~Violations of the following codes are representative of this category:~~

~~**HEALTH AND SAFETY CODE**~~

~~11352 Importing, Selling, Furnishing Controlled Substance~~

~~11353 Adult Inducing Minor to Violate Provisions~~
~~11379 Transporting, Importing, Selling Controlled Substance~~
~~11380 Adult Using, Soliciting or Intimidating Minor for Violation~~

MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent ~~owner~~ shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent ~~owner~~ shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five (5) days of disposition.

~~**Option:**~~ Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Suspension

License number _____, issued to respondent _____is suspended for a period of _____days beginning the effective of this decision.

Respondent shall cease all ~~pharmacy~~ operations as a [insert license type] during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent, is revoked; however, the revocation is stayed and respondent is placed on probation for _____years ~~upon~~ on the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____years ~~upon~~ on the following terms and conditions:

Surrender

Respondent ~~owner~~ surrenders license number _____as of the effective date of this decision. Respondent ~~owner~~ shall relinquish the premises wall license and renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent ~~owner~~ shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed and approved by the board of all controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent ~~owner~~ shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

~~Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.~~

~~Respondent owner understands and agrees that if he or she [he/she] ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.~~

Respondent may only seek a new or reinstated license from the board by way of a new application for licensure. Respondent shall not be eligible to petition for reinstatement of licensure.

Respondent ~~owner~~ may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

Respondent ~~owner~~ further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of $_____within _____days of the effective date of this decision.

~~**OPTION 1:**~~ (To be included if the respondent is a pharmacy.) Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the

pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Option 2: Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____shall be paid to the board prior to issuance of the new license.

Public ~~Reprimand~~ Reproval

It is hereby ordered that a public ~~reprimand~~ reproval be issued against licensee, _____. Respondent ~~owner~~ is required to report this reproval as a disciplinary action.

~~**Adoption of Stipulation**~~

~~It is understood by respondent owner that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Definition: Respondent
~~1~~ 2. Obey All laws
~~2~~ 3. Report to the Board
~~3~~ 4. Interview with the Board
~~4~~ 5. Cooperate with Board Staff
~~5~~ 6. Reimbursement of Board Costs
~~6~~ 7. Probation Monitoring Costs
~~7~~ 8. Status of License
~~8~~ 9. License Surrender While on Probation/Suspension
10. Sale or Discontinuance of Business
~~9~~ 11. Notice to Employees
~~10~~ 12. Owners and Officers: Knowledge of the Law
13. Premises Open for Business
~~11~~ 14. Posted Notice of Probation
~~12~~ 15. Violation of Probation
~~13~~ 16. Completion of Probation

OPTIONAL CONDITIONS
17. Suspension
~~14.~~ 18. Community Services Program
~~15.~~ 19. Restitution
~~16.~~ 20. Separate File of Records
~~17.~~ 21. Report of Controlled Substances
~~18.~~ 22. Surrender of DEA Permit
~~19.~~ 23. Posted Notice of Suspension
24. Destruction of Dangerous Drugs and/or Dangerous Devices
25. No Additional Ownership or Management of Licensed Premises

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Definition: Respondent

For the purposes of these terms and conditions, "respondent" shall refer to [insert name], ~~and~~ ~~a~~All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

~~1~~ 2. Obey All Laws

Respondent ~~owner~~ shall obey all state and federal laws and regulations.

Respondent ~~owner~~ shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo ~~contender~~ contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;

- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug~~,~~ and/or dangerous device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

~~2~~ 3. Report to the Board

Respondent ~~owner~~ shall report to the board quarterly, on a schedule and in a form or format as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent ~~owner~~ shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

~~3~~ 4. Interview with the Board

Upon receipt of reasonable prior notice, respondent ~~owner~~ shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

~~4~~ 5. Cooperate with Board Staff

Respondent ~~owner~~ shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

~~5~~ 6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent ~~owner~~ shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent ~~owner~~ shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

~~The filing of bankruptcy by respondent owner shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~**OPTION:**~~ Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

~~6~~ 7. Probation Monitoring Costs

Respondent ~~owner~~ shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~7~~ 8. Status of License

Respondent ~~owner~~ shall, at all times while on probation, maintain current [insert license type] ~~licensure~~ with the board. ~~If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board.~~ Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

~~8~~ 9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent ~~owner~~ wish to discontinue business, respondent ~~owner~~ may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

OPTION ~~(To be included if the respondent is a pharmacy)~~: Upon acceptance of the surrender, respondent ~~owner~~ shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent ~~owner~~ shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the board.

Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)

days.

Respondent ~~owner~~ may not apply for any new ~~licensure~~ license from the board for three (3) years from the effective date of the surrender. Respondent ~~owner~~ shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent ~~owner~~ further stipulates that ~~he or she~~ it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed ~~by~~ by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

~~9~~ 11. Notice to Employees

Respondent ~~owner~~ shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent ~~owner~~ shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent ~~owner~~ shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to ~~submit~~ timely provide such notification to employees, or to timely submit such notification to the board, shall be considered a violation of probation.

> "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

~~10~~ 12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and ~~any~~ all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a [insert license type] in

California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a [insert license type] for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a [insert license type] in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

~~11~~14. Posted Notice of Probation

Respondent ~~owner~~ shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. ~~The probation notice shall remain posted during the entire period of probation.~~

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~Failure to post such notice shall be considered a violation of probation.~~

~~12~~ 15. Violation of Probation

If ~~a~~ respondent ~~owner~~ has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent ~~license~~, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent ~~owner~~ violates probation in any respect, the board, after giving respondent ~~owner~~ notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~13~~ 16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

~~14~~ 17. Suspension

As part of probation, respondent's license to operate a [insert license type] is suspended for _____[day(s)/month(s)/year(s)] beginning the effective date of this decision. Respondent shall cease all operations as a [insert license type] during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

~~14.~~ ~~19.~~18. Community Service~~s~~ Program

Within sixty (60) days of the effective date of this decision, respondent ~~owner~~ shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least _____hours per _____for the first _____of probation.

Within thirty (30) days of board approval thereof, respondent ~~owner~~ shall submit documentation to the board demonstrating commencement of the community service program. Respondent ~~owner~~ shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~15.~~ ~~20.~~19. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____days of the effective date of this decision, respondent ~~owner~~ shall pay restitution to _____in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~16.~~ ~~21.~~20. Separate File of Controlled Substances Records

Respondent ~~owner~~ shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~17.~~ ~~22.~~21. Report of Controlled Substances

Respondent ~~owner~~ shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent ~~owner~~ shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent ~~owner~~ shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~18.~~ ~~23.~~22. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent ~~pharmacy~~ shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent ~~pharmacy~~ shall provide documentary proof of such cancellation to the board or its designee. Thereafter, respondent ~~pharmacy~~ shall not apply/reapply for a DEA

registration number without the prior written consent of the board or its designee.

Option**:** Respondent ~~pharmacy~~ may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option**:** Respondent ~~pharmacy~~ shall not order, receive, or retain any federal order forms, including DEA Form 222 ~~forms~~, for controlled substances.

~~19.~~ ~~18.~~23. Posted Notice of Suspension

Respondent ~~owner~~ shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public within two (2) days of receipt thereof from the board or its designee. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation.

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

24. Destruction of Dangerous Drugs and/or Dangerous Devices [To be used when the violations include misbranded or adulterated drugs.]

Respondent shall, by the effective date of this decision, arrange for the destruction of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and devices by a waste management company or reverse distributor. All products must be inventoried with an exact count prior to destruction. Respondent shall provide written proof of such destruction within five days of disposition.

Option: [To be used when the integrity, quality and strength of compounded drug products is at issue]

Respondent shall, by the effective date of this decision, arrange for the destruction of all compounded drug products and the components used to compound drug products by a waste management company. Respondent shall provide written proof of such destruction within five days of disposition. The Board or its designee shall have the right to retain a sample(s) of any and all compounded drug products or components used to compound drug products by Respondent.

25. No Additional Ownership or Management of Licensed Premises

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm , partnership, or corporation currently or hereinafter licensed by the board except as approved by the board or its designee. Violations of this restriction shall be considered a violation of probation.

~~6/2007~~ ~~7/2015~~ 10/2015

Attachment 10

Drug Warnings

16 CCR § 1744

Title 16. Board of Pharmacy

Modified Language

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because ~~T~~the following classes of drugs may impair a person's ability to ~~drive~~ operate a ~~motor~~ vehicle or vessel, ~~operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

(1) Muscle relaxants.

(2) ~~Analgesics with central nervous system depressant effects.~~

~~(3)~~ Antipsychotic drugs with central nervous system depressant effects ~~including phenothiazines~~

(~~4~~3) Antidepressants with central nervous system depressant effects.

(~~5~~4) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(~~6~~5) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~

(~~7~~6) Anticholinergic agents ~~and other drugs which~~ that may impair vision.

(7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel.

(b) Because ~~T~~the following ~~are examples~~ classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall ~~provide a written warning notice on the label to~~ include a written label on the drug container to alert the patient about possible potentiating effects: ~~which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:~~

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

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

(5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

(6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022~~, 4055~~ and 4074, Business and Professions Code.

Attachment 11

Patient-Centered Labels

16 CCR § 1707.5

Title 16. Board of Pharmacy

Second Modified Text

Changes made to the originally proposed text are shown by double strikethrough for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the first modified text are shown by bold wavy underline for added language. (Additionally, the modified text is listed in purple for color printers.)

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted~~ into the parentheses~~. If, ~~it has been at least five years since the expiration of the brand name's patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, **may list** the name of the manufacturer.

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

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

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services <u>and translation services</u> in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

~~(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.~~

~~(f)~~ (e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

Attachment 12

Continuing Eduction

16 CCR § 1732.05, 1732.2, & 1732.5

Title 16. BOARD OF PHARMACY

Modified Language

Initial proposed changes indicated with ~~single strikethrough~~ for deletions and single underline for additions.

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

Proposal to amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.05. Accreditation Agencies for Continuing Education

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

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

Proposal to amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on

an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

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

Proposal to amend § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5 Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least ~~six (6)~~ two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. ~~in one or more of the following subject areas:~~

~~(1) Emergency/Disaster Response~~

~~(2) Patient Consultation~~

~~(3) Maintaining Control of a Pharmacy's Drug Inventory~~

~~(4) Ethics~~

~~(5) Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility~~

~~(6) Compounding~~

Pharmacists renewing their licenses which expire on or after July 1, ~~2018~~ 2019, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

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

Attachment 13

Delegation of Certain Functions 16 CCR § 1703

Title 16. Board of Pharmacy

PROPOSED LANGUAGE

Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title 1, California Code of Regulations Section 100; and approve waivers pursuant to Section 4076.5(e) 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.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003, 4076.5 and 4311, Business and Professions Code.

Attachment 14

Inventory Reconciliation Report

16 CCR § 1715.65

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
    1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
    2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
    3) A comparison of (1) and (2) to determine if there are any variances; and
    4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
d) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.
e) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years.
f) A new pharmacist-in-charge of a pharmacy shall complete an inventory within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
g) For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.
h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:
    1) All controlled substances added to an automated drug delivery system are accounted for;
    2) Access to automated drug delivery systems is limited to authorized facility personnel;

3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
4) Confirmed losses of controlled substances are reported to the board; and
5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Attachment 15

Self-Assessment

16 CCR 1715, 1784

Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

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

(c) The components of this assessment shall be on Form 17M-13 ~~(Rev. 10/14)~~ (Rev. 10/16) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 ~~(Rev. 10/14)~~ (Rev. 10/16) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.

Amend Section 1784 in Article 10 of Division 17 of Title 16 to read:

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

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 ~~(Rev. 10/14)~~ (Rev. 10/16) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.

(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

COMMUNITY PHARMACY SELF-ASSESSMENT
HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily available ~~and retained~~ in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~02/12~~ 10/16).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐
Non-Licensed Owner ☐ Other (please specify) ☐

~~Permit~~ License #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding ~~Permit~~ License# _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. ~~APP~~ APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ TCH # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

_____
PIC Initials

COMMUNITY PHARMACY SELF-ASSESSMENT
HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

☐☐☐ 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)

☐☐☐ 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)

☐☐☐ 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714)

☐☐☐ 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)

☐☐☐ 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. 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. A pharmacy may also provide this information in a video in lieu of the poster. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR ~~1707.2~~ 1707.6)

☐☐☐ 1.8. ~~Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])~~ "Point to Your Language" poster is posted in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6(c))

☐☐☐ ~~1.8~~ 1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~1.9~~ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

PIC Initials _____

☐☐☐ ~~1.10~~ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete section 27 – "Compounding.")

Yes No N/A

☐☐☐ ~~1.11~~ 1.12. The pharmacy has procedures in place to take 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&PC 4104[a])

☐☐☐ ~~1.12~~ 1.13. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ ~~1.13~~ 1.14. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ ~~1.14~~ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

☐☐☐ ~~1.15~~ 1.16. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

☐☐☐ 2.2. 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: (B&PC 4059.5[f]):

- ☐ 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- ☐ 2.2.2. 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 (B&PC 4059.5[f][2]);
- ☐ 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- ☐ 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- ☐ 2.2.5. 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. B&PC 4059.5[f][5])

☐☐☐ 2.3 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (Title II of the DQSA Section 582[d])

☐☐☐ 2.4 Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (Title II of the DQSA Section[d][ii])

☐☐☐ 2.5 The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (Title II of the DQSA Section 582[d][iii])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q], CCR 1714[b])

☐☐☐ 3.2. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

- ☐ 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.
- ☐ 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.
- ☐ 3.2.3. Are not expired.

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

☐☐☐ 4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 29 [donate drugs] or Section 30 [operate program] of this Self-Assessment.)

5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (B&PC 4113(c), CCR 1709.1[b])

☐☐☐ 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ 5.4. Is the PIC in charge of another pharmacy?

_____
PIC Initials

☐☐☐ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

~~☐☐☐ 5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

☐☐☐ ~~5.8~~ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (H&SC 1206, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. ~~The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)~~

Only a pharmacist:

- ☐ transmits a valid prescription to another pharmacist (B&PC 4052)
- ☐ administers drugs and biological products ordered by the prescriber; (B&PC 4052)
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (B&PC 4052)
- ☐ provides professional information and participates in multidiscipline review of patient progress; (B&PC 4052)
- ☐ furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; (B&PC 4052 (a)(10), B&PC 4052(a)(11), 4052.01, B&PC 4052.3, B&PC 4052.8, 4052.9)
- ☐ responds to end of life option drugs (insert section??)
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052 (a)(12)

☐☐☐ 6.2. ~~The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))~~

Only a pharmacist:

- ☐ receives a new prescription order from the prescriber
- ☐ consults with the patient
- ☐ identifies, evaluates and interprets a prescription,
- ☐ interprets the clinical data in a patient medication record,
- ☐ consults with any prescriber, nurse, health professional or agent thereof,
- ☐ supervises the packaging of drugs,
- ☐ checks the packaging procedure and product upon completion,
- ☐ is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients,
- ☐ performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

☐☐☐ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or 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, is performing the following functions, in accordance with policies, procedures~~,~~ or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

☐☐☐ 6.4. Pharmacists are ~~able to~~ provided access to ~~information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through~~ the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraceptive pursuant to the statewide protocol found in 16 CCR 1746.

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (B&PC 1206.6)

Yes No N/A

☐☐☐ 6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (B&PC 1206.6)

CDPH (CLIA) Registration #:_____ Expiration: _____

☐☐☐ 6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

7. Duties of an Advance Practice Pharmacist

Yes No N/A

☐☐☐ ~~7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~7.2~~ 7.1. The advance practice pharmacist has received an advance practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~7.2.1~~ 7.1.1Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ☐ ~~7.2.2~~ 7.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ ~~7.2.2~~ 7.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ☐ ~~7.2.2~~ 7.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

Yes No N/A

☐☐☐ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209, CCR 1726)

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. ~~Registered~~ ~~p~~Pharmacy technicians ~~are performing~~ only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or ~~her self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

☐☐☐ 9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7],~~ B&P 4052[a][8], CCR 1707.2)~~:~~

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request; and
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.
- ☐ 11.1.5. unless a patient declines the consultation directly to the pharmacist.

☐☐☐ 11.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ 11.4. Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Prescription Requirements

Yes No N/A

☐☐☐ 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)

☐☐☐ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (B&PC 4070, CCR 1717)

☐☐☐ 12.3. If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

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PIC Initials

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (B&PC 4040[c])

☐☐☐ 12.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

☐☐☐ 12.8. With the exception of those prescriptions written under H&SC 11159.2 and H&SC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], H&SC 11167.5)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11120[e])

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1311.100, 1306.11)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (B&PC 4076)

☐☐☐ 13.2. The prescription label is formatted in accordance with CCR 1707.5.

~~☐☐☐ 13.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR 1707.5[a])~~

~~**Yes No N/A**~~

~~☐☐☐ 13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])~~

~~☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~

~~☐ 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a][2])~~

~~☐ 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])~~

PIC Initials

☐☐☐ ~~13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ 13.6. The ~~E~~expiration date~~s~~ of a ~~drugs'~~ drug's effectiveness ~~are~~ is consistent with those of the manufacturer ~~if the information is required on the original manufacturer's label~~. (B&PC 4076)

☐☐☐ 13.7. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

☐☐☐ 13.8. Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ 13.9. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or as otherwise allowed. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ 13.10. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 13.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 13.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.13. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.14. Medication guides are provided on required medications. (21 CFR 208.1)

☐☐☐ 13.~~14~~15. The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership.

☐☐☐ 13.~~15~~16. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

Yes No N/A

☐☐☐ 13.~~16~~17. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

☐☐☐ 13.18. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)

☐☐☐ 13.~~17~~ 19. The pharmacy dispenses not more than a 90-day supply of a dangerous drug with the following exceptions medications~~(other than controlled substances, or psychotropic medication or drugs)~~: (B&PC 4064.5)

- Controlled substances

PIC Initials

- Psychotropic medications
- Self-administered hormonal contraception

☐ 13.~~17~~ 20.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (B&PC 4064.5[a])

☐ 13.~~17~~20.1.1 The prescriber has not indicated "no change to quantity" or words of similar meaning; (B&PC 4064.5[d])

☐ 13.~~17~~20.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

☐ 13.~~17~~20.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13.~~17~~20.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

☐ 13.~~17~~20.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.~~17~~20.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐☐☐ 13.~~18~~21. The pharmacist includes 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 may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b], CCR 1744)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ 14.2. Refills are documented. (CCR 1717)

☐☐☐ 14.3. Prescriptions for dangerous drugs or devices are filled 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&PC 4064)

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

PIC Initials

Yes No N/A

☐☐☐ ~~14.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 15.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ 15.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ☐ 15.6.1. Date, location, and participants in the quality assurance review;
- ☐ 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 15.6.3. Findings and determinations; and
- ☐ 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 15.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 15.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials _____

16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 16.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐☐☐ 16.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

☐☐☐ 16.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

~~☐☐☐ 16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])~~

☐☐☐ 16.~~5~~ 4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

~~☐☐☐ 16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Prescription Transfer

Yes No N/A

☐☐☐ 17.1. Only pharmacists may transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

☐☐☐ 17.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

☐☐☐ 17.3. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

PIC Initials

Yes No N/A

☐☐☐ 17.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ 18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ 18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ 18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ 18.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐☐☐ 18.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ 18.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Record Keeping Requirements

Yes No N/A

☐☐☐ 19.1. ~~A~~ All completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ 19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

- ☐ 19.2.1. Prescription records (B&PC 4081[a])
- ☐ 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- ☐ 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ☐ 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

☐ 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

☐☐☐ 19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4145.5)

☐ 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

☐ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

☐ 19.3.3. The sale of hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145.5)

☐ 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)

☐ 19.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of ~~30 or fewer~~ hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

☐☐☐ 19.4. When hypodermic needles and syringes are furnished by a pharmacy ~~or hypodermic needle and exchange program~~ without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

☐☐☐ 19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 19.6. The pharmacy ~~dispenses~~ furnish epinephrine auto-injector to an authorized entity ~~a prehospital emergency medical care person or lay rescuer~~ for the purpose of rendering emergency care in accordance with H&SC 1797.197a (B&PC 4119.3, 4119.4)

PIC Initials

☐ 19.6.1.A ~~physician/surgeon~~ authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119.3[a][1], 4119.4)

☐ 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only", the dosage, use and expiration date. (B&PC 4119.3[a][1], 4119.4)

☐ 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2], 4119.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. DEA Controlled Substances Inventory

Inventory:

Yes	No	N/A	
☐	☐	☐	20.1. Is completed biennially (every two years). Date completed: _____ (21 CFR 1304.11[b])
☐	☐	☐	20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])
☐	☐	☐	20.3. All completed inventories are ~~is~~ available for inspection for three years. (CCR 1718)
☐	☐	☐	20.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a])
☐	☐	☐	20.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])
☐	☐	☐	20.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])
☐	☐	☐	20.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)
☐	☐	☐	20.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)
☐	☐	☐	20.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing

registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

Yes No N/A

☐☐☐ 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. B&PC 4160)

☐☐☐ 20.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

☐☐☐ 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ 20.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ 20.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

☐☐☐ 20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

21. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 21.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ 21.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

- ☐ 21.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- ☐ 21.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- ☐ 21.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- ☐ 21.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ 21.3. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

☐☐☐ 21.4. The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill." (21 CFR 1306.13[b], CCR 1745)

☐☐☐ 21.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written when requested by the patient or practitioner. (21 USC 829[f])

☐☐☐ 21.~~5~~6. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

☐☐☐ 21.~~6~~7. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

PIC Initials _____

☐☐☐ 21.~~7~~8. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

☐☐☐ 21.~~8~~9. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

Yes No N/A

☐☐☐ 21.~~9~~10. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

☐☐☐ 21.~~10~~11. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

☐☐☐ 21.~~11~~12. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 21.~~12~~13. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ 22.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ 22.2. The pharmacy has registered with the board all automated drug delivery systems that it operates in any location within 30 days of installation, removal, and at the time of renewal. (B&PC 4105.5(b))

☐☐☐ 22.3. The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. (B&PC 4105.5(c))

☐☐☐ 22.4. The pharmacy reports drugs losses as required by law. (B&PC 4105.5(c))

☐☐☐ 22.~~2~~3. The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342, 21 CFR Part 201.17, H&SC 111355)

PIC Initials

☐☐☐ 22.~~3~~4. For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

- ☐ 22.3.1. Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])
- ☐ 22.3.2. A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])
- ☐ 22.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

☐☐☐ 22.4. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

- ☐ 22.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])
- ☐ 22.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 23.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

☐☐☐ 23.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐☐☐ 23.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Refill Pharmacy

Yes No N/A

☐☐☐ 24.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ 24.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 24.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is “no” or “not applicable” go to section 23.

☐☐☐ 24.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ 24.5. Refill prescription label meets requirements of B&PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ 24.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

Yes No N/A

☐☐☐ 24.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 24.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ 24.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

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Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 25.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

☐ 25.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

☐ 25.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

☐ 25.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

☐ 25.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ 25.2. The pharmacy meets the following requirements:

☐ 25.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])

☐ 25.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])

☐ 25.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])

☐ 25.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])

☐ 25.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])

☐ 25.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])

☐ 25.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])

☐ 25.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])

☐ 25.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])

☐ 25.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])

☐ 25.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

☐ 25.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

PIC Initials _____

26. Policies and Procedures

Yes No N/A

☐☐☐ 26.1. There are written policies and procedures in place for:

☐ ~~26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order or state protocol for immunizations; (B&PC 4052.1[a][3])~~

☐ 26.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[a],[c])

☐ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[b],[c])

☐ 26.1.4. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

☐ 26.1.5. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 26.1.6. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ 26.1.7. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (B&PC 4059.5[f][1])

☐ 26.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ 26.1.9. Reporting requirements to protect the public; (B&PC 4104)

☐ 26.1.10. ~~Preventing the dispensing of a prescription drug that is contrary to the law;~~ A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (B&PC 733)

Comment [AFS1]: Giny will research

☐ 26.1.11. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (B&PC 733)

☐ 26.1.12. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

PIC Initials

Yes No N/A

☐☐☐ 26.2. Does your pharmacy employ the use of a common electronic file?

☐ 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][1]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

☐ 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)

☐ 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)

☐ 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

☐ 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐ 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])

☐ 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)

☐ 26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐☐☐ 26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a], CCR 1746.3)

☐ 26.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

☐ 26.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

☐☐☐ 26.4. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.9, CCR 1746.2)

PIC Initials

☐☐☐ 26.4. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.3, CCR 1746.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Compounding

Yes No N/A

☐☐☐ 27.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. ~~02/12~~ 10/16) (CCR 1735.2~~[j])~~

28. Nuclear Pharmacy

Yes No N/A

☐☐☐ 28.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ 28.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ 28.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. ~~02/12~~ 10/16.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

29. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

☐ 29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

☐ 29.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

☐☐☐ 29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

☐ 29.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

☐ 29.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])

☐ 29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 29.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

☐ 30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H&SC 150201[a][1])

☐ 30.1.1.1 Is county owned (H&SC 150201[b][1]) or

☐ 30.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[b][1], 150200)

☐ 30.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

Yes No N/A

☐☐☐ 30.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: _____ Date: _____

PIC Initials

☐☐☐ 30.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H&SC 150204[a][3])

☐☐☐ 30.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ 30.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

Drugs and Maintenance of Drug Stock

☐☐☐ 30.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

☐☐☐ 30.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

☐☐☐ 30.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

☐☐☐ 30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])

☐ 30.9.1. Are received from authorized sources. (H&SC 150202, 150203)

☐ 30.9.2. No controlled substances are received. (H&SC 150204[c][1])

☐ 30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])

☐ 30.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])

☐ 30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])

☐ 30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])

☐ 30.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

Yes No N/A

☐☐☐ 30.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

PIC Initials _____

Transferring Donated Drugs From One Participating Entity to Another

☐☐☐ 30.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

☐☐☐ 30.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ 30.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

☐☐☐ 30.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

☐☐☐ 30.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients

☐☐☐ 30.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

☐☐☐ 30.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

PIC Initials

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. ~~10/14~~ 10/16 must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~02/12~~ 10/16).)

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

Pharmacy staff (pharmacists, interns, technicians):
APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date:_____
~~APP~~ APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ INT # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

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PIC
Initials

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)

☐☐☐ 1.2. The pharmacy has procedures in place to take 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&PC 4104[a])

☐☐☐ 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ 1.5. The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐☐☐ 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

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PIC
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Yes No N/A

☐☐☐ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

☐☐☐ 1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?
(~~If yes, complete section 27 – "Compounding"~~) (If yes, complete Compounding Self-Assessment Form 17M-39 10/16)

☐☐☐ 1.13. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

☐☐☐ 2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ 2.2. The pharmacist, intern, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (B&PC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

☐ 2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

☐ 2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____
PIC Initials

3. Delivery of Drugs

Yes No N/A

☐☐☐ 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ 3.2. 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 premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

☐☐☐ 3.3. 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 (B&PC 4059.5[f]):

- ☐ 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- ☐ 3.3.2. 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 (B&PC 4059.5[f][2]);
- ☐ 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- ☐ 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- ☐ 3.3.5. 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. (B&PC 4059.5[f][5])

☐☐☐ 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (Title II of the DQSA Section 582[d][i])

☐☐☐ 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (Title II of the DQSA Section 582[d][ii])

☐☐☐ 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (Title II of DQSA Section 582[d][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

4. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

Yes No N/A

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b]

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)

- ☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
- ☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- ☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- ☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

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PIC Initials

☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])

☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 709, 1709.1)

☐☐☐ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.1[b])

☐☐☐ 6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

~~☐☐☐ 6.5. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 [d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. 7.1. ~~Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure~~

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PIC Initials

~~that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4052, 4052.2, CCR 1793.1)~~ Only a pharmacist: (BPC 4052, BPC 4052.2, CCR 1717(c), CCR 1793.1)

- ~~The pharmacist~~ ~~r~~Receives a chart order for an inpatient;
- Identifies, evaluates and interprets the chart order;
- Reviews patient's drug regimen and interprets the clinical data in the patient's medication record;
- Consults with any prescriber, nurse or health care professional;
- Calculates drug doses;
- Supervises the packaging of drugs and checks the packaging procedures and products upon completion;
- Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients;
- Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment.

☐☐☐ 7.2 7.2. ~~Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2.~~ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (B&PC 4027, 4051, 4052, 4052.2)

- Ordering or performing routine drug therapy-related patient assessment procedures;
- Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection;
- Initiating or adjusting the drug regimen of a patient;
- Performing moderate or waived laboratory tests. (Prior to performing any of these functions, the pharmacist must have either (1) successfully completed

clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2)

☐☐☐ 7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ ~~8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~8.2~~.8.1 The advance practice pharmacist has received an advance practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~8.2.1~~ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.3 Initiate drug therapy and 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; (B&PC 4052.6[b])
- ☐ ~~8.2.1~~ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ ~~8.2.1~~ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ☐ ~~8.2.1~~ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

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PIC Initials

☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)

☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c]

Yes No N/A

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned when applicable. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2)

☐☐☐ 10.2. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

☐☐☐ ~~10.2~~ 10.3. ~~The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, w~~When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ ~~10.2~~ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

☐☐☐ ~~10.2~~ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her ~~self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~10.2~~ 10.6. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

~~☐☐☐ 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)~~

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PIC Initials

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])

Yes No N/A

☐☐☐ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- ☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- ☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

☐☐☐ 11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- ☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ☐ 12.1.2. Repackaging and compounding records;
- ☐ 12.1.3. Physician orders;
- ☐ 12.1.4. Wards, nursing stations and night stock medications;
- ☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ☐ 12.1.6. Bedside medications;
- ☐ 12.1.7. Emergency drug supply;
- ☐ 12.1.8. Pass medications;
- ☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ☐ 12.1.10. Routine distribution of inpatient medications;
- ☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ☐ 12.1.12. Handling of medication when pharmacist not on duty; and
- ☐ 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ☐ 12.2.1. Destruction of controlled substances; and
- ☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

Yes No N/A

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication and ~~parenteral admixtures~~ compounded preparations are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076, CCR 1735.4, CCR 1751.2)

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

15. Duration of Drug Therapy

Yes No N/A

☐☐☐ 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

☐☐☐ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

☐☐☐ 16.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

17. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

Yes No N/A

☐☐☐ 17.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

- ☐ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 17.6.3. Findings and determinations;
- ☐ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 17.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. ~~A~~ All completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and is maintained for three years. (CCR 1715)

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

- ☐ 18.2.1. Prescription records (B&PC 4081[a])
- ☐ 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])

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PIC Initials

☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)

☐ 18.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)

☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ 18.2.8. Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1]), 150204(k), B&PC 4105(c).

Yes No N/A

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503, B&PC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)

☐☐☐ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

☐☐☐ ~~18.6~~ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ ~~18.6~~ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ ~~18.6~~ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ ~~18.6~~ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

☐☐☐ ~~18.6~~ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ ~~18.6~~ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one

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PIC
Initials

year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

☐☐☐ ~~18.6~~ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ ~~18.6~~ 18.14. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. After-Hours Supply of Medication

Yes No N/A

☐☐☐ 19.1. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ 20.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ 20.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐☐☐ 20.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ 20.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

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21. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ 21.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Emergency Room Dispensing

Yes No N/A

☐☐☐ 22.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (B&PC 4068[a])

- ☐ 22.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 22.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 22.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 22.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;
- ☐ 22.1.5.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; and
- ☐ 22.1.6. 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;

☐☐☐ 22.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ 22.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ 22.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ 22.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

☐☐☐ 22.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)

☐☐☐ 22.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

☐☐☐ 22.8. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 22.9. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ 23.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ 23.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ 23.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)

~~☐☐☐ 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])~~

~~☐☐☐ 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ 23.~~6~~4. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ 23.~~7~~5. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

_____
PIC Initials

☐☐☐ 23.~~8~~6. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ 23.~~9~~7. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ 23.~~10~~8. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 23.~~11~~9. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 23.~~12~~10. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 23.~~13~~11. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 23.~~14~~12. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ 24.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

☐☐☐ 24.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy:

If the answer to this and the previous question is "no" or "not applicable" go to Section ~~23.~~ 25.

☐☐☐ 24.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ 24.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

_____
PIC Initials

☐☐☐ 24.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ 24.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ 24.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

25. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ 25.1. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located ~~packages unit dose medication for inpatients of one or more hospitals under common ownership~~ within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

- ☐ 25.1.1. _____ Distance (miles): _____
- ☐ 25.1.2. _____ Distance (miles): _____
- ☐ 25.1.3. _____ Distance (miles): _____
- ☐ 25.1.4. _____ Distance (miles): _____
- ☐ 25.1.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.
- ☐ 25.1.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to Section 4128.4.
- ☐ 25.1.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

☐☐☐ 25.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

☐☐☐ 25.3. ~~All~~ Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded ~~and readable~~ to be machine readable at the inpatient's bedside using barcode medication administrative software. ~~The barcode information contains the required information~~: (B&PC 4128.4)

- ☐ ~~25.3.1. The date the medication was prepared.~~ The barcode medication administration software shall permit health care practitioners to ensure, 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.
- ☐ ~~25.3.2. The components used in the drug product.~~ The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the patient.
- ☐ ~~25.3.3. The lot number or control number.~~

_____
PIC Initials

☐ ~~25.3.4. The expiration date.~~

☐ ~~25.3.5. The National Drug Code Directory number.~~

☐ ~~25.3.6. The name of the centralized hospital packaging pharmacy.~~

Yes No N/A

☐☐☐ 25.4. ~~The~~ Any label for each unit dose medication produced by a centralized hospital packaging pharmacy ~~contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements~~ displays a human-readable label that contains the following: (B&PC 4128.5)

☐ 25.4.1 The date the medication was prepared.

☐ 25.4.2 The beyond-use date

☐ 25.4.3 The establishd name of the drug.

☐ 25.4.4 The quantity of each active ingredient.

☐ 25.4.6 The lot number or control number assigned by the centralized hospital packaging pharmacy.

☐ 25.4.5 Special storage or handling requirements.

☐ 25.4.7 The name of the centralized hospital packaging pharmacy.

☐☐☐ 25.5 The pharmacist is able to retrieve all of the following information using the lot number or control number: (B&PC 4128.5)

☐ 25.5.1 The components used in the drug product.

☐ 25.5.2 The expiration date of each of the drug's components.

☐ 25.5.3 The National Drug Code Directory number.

☐☐☐ 25.~~5~~6. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

26. Policies and Procedures

Yes No N/A

☐☐☐ 26.1. There are written policies and procedures in place for:

_____
PIC
Initials

☐ 26.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.

☐ 26.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])

☐ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (B&PC 4104[b])

☐ 26.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])

☐ 26.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].

☐ 26.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])

☐ 26.1.7. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐ 26.1.8. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])

☐ 26.1.9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Compounding

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. ~~02/12~~ 10/16). (CCR 1735.2~~[j]~~[i])

_____
PIC Initials

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

_____
PIC
Initials

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations),* at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834
(916) 574-7900 FAX (916) 574-8618

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

CA Wholesaler Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours ○

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License #_____ Expiration Date_____

Website Address (optional):_____

DRAFT

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

2. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

3. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

4. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

5. _____ ~~DR#~~EXE/RPH#_____ _____ Exp. Date

6. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

7. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

8. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

9. _____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

10_____ ~~DR~~EXE#/RPH#_____ _____ Exp. Date

DRAFT

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly

☐ ☐ ☐ 2.1.2. Are well ventilated

☐ ☐ ☐ 2.1.3. Are free from rodents and insects

☐ ☐ ☐ 2.1.4. Are adequately lit

☐ ☐ ☐ 2.1.5. Have plumbing in good repair

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

DRAFT

Yes No N/A

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ 2.5. Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

2.6. The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

DRAFT

Yes No N/A

☐ ☐ ☐ 2.8. The facility is subscribed to the board's email ~~e-mail~~ notifications. (B&PC 4013)

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.9. The facility receives the board's email ~~e-mail~~ notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

☐ ☐ ☐ 3.2. Is the designated representative-in-charge at least 18 years of age and is responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d], 4053.1(b))

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

DRAFT

Yes No N/A

☐ ☐ ☐ 3.5. The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative/Pharmacist

Yes No N/A

☐ ☐ ☐ If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

☐ ☐ ☐ 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

☐ ☐ ☐ 5.3. For license verification, the wholesaler may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

DRAFT

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 6.1. When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])

☐ ☐ ☐ 7.2. Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)

☐ ☐ ☐ 7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])

☐ ☐ ☐ 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

DRAFT

Yes No N/A

☐ ☐ ☐ 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a][b][d], B&PC 4169)

_____

_____

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 8.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 8.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

DRAFT

Yes No N/A

☐ ☐ ☐ 8.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ 8.6.1. transacted with a business licensed with this board as a wholesaler or pharmacy?

☐ ☐ ☐ 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 8.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

_____

_____

~~Yes No N/A~~

~~☐ ☐ ☐ 8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).~~

Yes No N/A

☐ ☐ ☐ <u>8.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (Title II of the DQSA Section 582[c])</u>

DRAFT

☐ ☐ ☐ 8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

Yes No N/A

☐ ☐ ☐ 8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

☐ ☐ ☐ 8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

_____

_____

☐ ☐ ☐ 8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

☐☐☐ 9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

☐☐☐ 9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

DRAFT

Yes No N/A

☐☐☐ 9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

☐ 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])

☐ 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

10. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 10.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

10.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

11. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 11.1. Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

DRAFT

Yes No N/A

☐ ☐ ☐ 11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059.5[d])

☐ ☐ ☐ 11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

☐ ☐ ☐ 11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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12. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ 12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 12.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

☐ ☐ ☐ 12.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 12.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

DRAFT

12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 12.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 12.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

☐ ☐ ☐ 12.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

☐ ☐ ☐ 12.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

☐ ☐ ☐ 12.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 12.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 12.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

DRAFT

Yes No N/A

☐ ☐ ☐ 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☐ 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, CFR 1305.17[c], 1305.17[a] [b], and H&SC 11252, 11253, 1304.03)

☐ ☐ ☐ 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])

☐ ☐ ☐ 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

DRAFT

Yes No N/A

☐ ☐ ☐ 12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

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13. Policies and Procedures

13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 13.1.1. Receipt of drugs

☐ ☐ ☐ 13.1.2. Security of drugs

☐ ☐ ☐ 13.1.3. Storage of drugs-(including maintaining records to document proper storage)

☐ ☐ ☐ 13.1.4. Inventory of drug-(including correcting inaccuracies in inventories)

☐ ☐ ☐ 13.1.5. Distributing drugs

☐ ☐ ☐ 13.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 13.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 13.1.9. drugs that have been partially used~~?~~

☐ ☐ ☐ 13.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

☐ ☐ ☐ 13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

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14. Training

Yes No N/A

☐ ☐ ☐ 14.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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15. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~15.~~ 16.

☐ ☐ ☐ 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])

☐ ☐ ☐ 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐ 15.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

☐ ☐ ☐ 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

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16. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])

☐ ☐ ☐ 16.2.~~1.~~ Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (Title II of the DQSA Section 582[c])

☐ ☐ ☐ 16.3.~~2.~~ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) ~~Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.~~

☐ ☐ ☐ 16.4.~~3.~~ Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

☐ ☐ ☐ 16.5.~~4.~~ Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

☐ ☐ ☐ 16.6.~~5.~~ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

☐ ☐ ☐ 16.7.~~6.~~ Are required records stored off-site only if a board issued written waiver has been granted?

16.8.~~7.~~ If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ 16.9.~~8.~~ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 16.10.~~9.~~ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 16.11.~~10.~~ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ 16.12.~~11.~~ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

DRAFT

Yes No N/A

☐ ☐ ☐ 16.13.~~12.~~ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):

_____

_____

☐ ☐ ☐ 16.14.~~13.~~ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

☐ ☐ ☐ 16.15.~~14.~~ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

☐ ☐ ☐ 16.16.~~15.~~ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

17. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 17.1. A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c].

☐ ☐ ☐ 17.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B&PC 4305.5[a])

☐ ☐ ☐ 17.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 17.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

DRAFT

Yes No N/A

☐ ☐ ☐ 17.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 17.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])

☐ ☐ ☐ 17.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])

☐ ☐ ☐ 17.8. Effective January 1, 2006 your business will develop and maintain a tracking system for 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. Your system must:

1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
2. identify purchases of any dangerous drugs at preferential or contract prices
3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B&PC 4164[b])

☐ ☐ ☐ 17.9. I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])

☐ ☐ ☐ 17.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 17.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

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18. Additional Licenses/Permits Required

18.1. List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

~~**California Board of Pharmacy**~~
~~1625 N. Market Blvd., Suite N219~~
~~Sacramento, CA 95834~~
~~Phone: (916) 574-7900~~
~~Fax: (916) 574-8618~~
~~www.pharmacy.ca.gov~~

~~***Pharmacy Law*** may be obtained by contacting:~~
~~LawTech Publishing Co.~~
~~1060 Calle Cordillera, Suite 105~~
~~San Clements, CA 92673~~
~~Phone: (800) 498-0911 Ext. 5~~
~~www.lawtechpublishing.com~~

~~**Pharmacist Recovery Program**~~
~~Phone: (800) 522-9198 (24 hours a day)~~

~~***Prescriber Boards:***~~

~~**Medical Board of California**~~
~~2005 Evergreen St., Suite 1200~~
~~Sacramento, CA 95815~~
~~Phone: (800) 633-2322~~
~~Phone: (916) 263-2382~~
~~Fax: (916) 263-2944~~
~~http://www.mbc.ca.gov~~

~~**Dental Board of California**~~
~~2005 Evergreen St., Suite 1550~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2300~~
~~Fax: (916) 263-2140~~
~~http://www.dbc.ca.gov~~

~~**Board of Registered Nursing**~~
~~1625 N. Market Blvd., Suite N217~~
~~Sacramento, CA 95834~~
~~Phone: (916) 322-7697~~
~~Fax: (916) 574-8637~~
~~http://www.rn.ca.gov/~~

~~**Board of Optometry**~~
~~2420 Del Paso Road, Suite 255~~
~~Sacramento, CA 95834~~
~~Phone: (916) 575-7170~~
~~Fax: (916) 575-7292~~
~~http://www.optometry.ca.gov/~~

~~**Osteopathic Medical Board of California**~~
~~1300 National Drive, Suite 150~~
~~Sacramento, CA 95834~~
~~Phone: (916) 928-8390~~
~~Fax: (916) 928-8392~~
~~http://www.ombc.ca.gov~~

~~**Physician Assistant Committee**~~
~~2005 Evergreen St., Suite 1100~~
~~Sacramento, CA 95815~~
~~Phone: (916) 561-8780~~
~~Fax: (916) 263-2671~~
~~http://www.pac.ca.gov~~

~~**Board of Podiatric Medicine**~~
~~2005 Evergreen St., Suite 1300~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2647~~
~~Fax: (916) 263-2651~~
~~http://www.bpm.ca.gov~~

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~~**Veterinary Medical Board**~~
~~2005 Evergreen St., Suite 2250~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2610~~
~~Fax: (916) 263-2621~~
~~http://www.vmb.ca.gov~~

~~***Federal Agencies:***~~

~~**Food and Drug Administration**~~
~~**– Industry Compliance**~~
~~http://www.fda.gov/oc/industry/centerlinks.html#drugs~~

~~The **Drug Enforcement Administration** may be contacted at:~~

~~**DEA Website:**~~
~~http://www.deadiversion.usdoj.gov~~
~~**Online Registration – New Applicants:**~~
~~http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm~~
~~**Online Registration – Renewal:**~~
~~www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm~~
~~**Registration Changes (Forms):**~~
~~http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html~~
~~**Online DEA 106 Theft/Loss Reporting:**~~
~~https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp~~
~~**Controlled Substance Ordering System (CSOS):** http://www.deaecom.gov/~~

~~**DEA Registration Support (all of CA):**~~
~~(800) 882-9539~~

~~**DEA – Los Angeles**~~
~~255 East Temple Street, 20th Floor~~
~~Los Angeles, CA 90012~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (213) 621-6942~~

~~**DEA – San Francisco**~~
~~450 Golden Gate Avenue, 14th Floor~~
~~San Francisco, CA 94102~~
~~Registration: (888) 304-3251~~
~~Theft Reports or Diversion: (415) 436-7900~~

~~**DEA – Sacramento**~~
~~4328 Watt Avenue~~
~~Sacramento, CA 95821~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~

~~**DEA – Riverside**~~
~~4470 Olivewood Avenue~~
~~Riverside, CA 92501-6210~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (951) 328-6200~~

~~**DEA – Fresno**~~
~~2444 Main Street, Suite 240~~
~~Fresno, CA 93721~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (559) 487-5406~~

~~**DEA – San Diego and Imperial Counties**~~
~~4560 Viewridge Avenue~~
~~San Diego, CA 92123-1637~~
~~Registration: (800) 284-1152~~
~~Diversion or Investigation: (858) 616-4100~~

~~**DEA – Oakland**~~
~~1301 Clay Street, Suite 460N~~
~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~

~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

~~**DEA – Redding**~~
~~310 Hensted Drive, Suite 310~~
~~Redding, CA 96002~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (530) 246-5043~~

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