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LEGISLATION AND REGULATION COMMITTEE REPORT

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LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee did not meet this quarter.

Part 1: LEGISLATION REPORT

a. Board Sponsored Legislation: Sunset Review Items Resulting in Possible Legislation

1. Statutory Fee Increase

   During this meeting, the board heard a report from the Organizational Development Committee regarding an analysis of the board's fund condition and fee structure. A copy of the statutory proposal was provided in the Organization Development materials.

2. Regulation of Outsourcing Facilities

   During this meeting, the Enforcement Committee provided an update on the board's proposal to establish a regulatory framework for the licensure of outsourcing facilities in and outside of California. The Senate Business and Professions Committee will evaluate outsourcing facilities as part of its evaluation of the impact of the DQSA during the board's sunset review. A legislative solution is likely to come as part of this review.

   Currently California is licensing as sterile compounding pharmacies federally licensed outsourcing facilities located within or shipping medication into California. This is increasingly losing its viability as a regulatory solution. First, it does not recognize the federal outsourcing requirements that permit large scale compounding. Second multiple states are moving to establish regulatory frameworks to license outsourcing facilities as separate entities, and some bar licensure of these facilities in their home states as sterile compounding pharmacies. This is currently an issue in Mississippi, will and be an issue in July in New Jersey. Several other states have pending legislation in this area as well.

In 2015, the board sponsored legislation (SB 619, Morrell) to license outsourcing facilities as separate entities both within and outside California to ship into the state. That bill was held in suspense by the Senate Appropriations Committee.

3. Registration of Automated Delivery Devices

As reported earlier during the Enforcement Committee portion of this meeting, the board received an update on and discussed the registration of automated dispensing machines or devices in various settings away from a licensed pharmacy or within a licensed facility.

California law currently permits the use of automated delivery devices which are mechanical systems controlled by a pharmacist or other specified health care providers to provide storage, dispensing and distribution of dangerous drugs and devices. Use of these delivery devices promotes control and the ability to maintain all transaction information, to accurately track the movement of drugs into and out of the device, for security, accuracy and accountability while providing for quality, potency and purity of the medications.

The board has no idea how many of these delivery devices are in use, where they are in use, or which pharmacy is responsible for specific delivery devices. The registration of these delivery devices would be a beneficial step in board oversight and enforcement. The list could be updated as needed via form submission to the board by a pharmacy adding, moving or removing a machine. The registration could operate much like the off-site storage waivers for records. Then, at annual renewal of the pharmacy, the pharmacy could update or confirm the list of machines it operates and where each is located.

Draft language for the registration of automated dispensing devices will be provided at the meeting.

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

ATTACHMENT 1

1. AB 45 (Mullin) Household Hazardous Waste

Last Amend:	January 21, 2016
Status:	Referred to Senate Environmental Quality (2/4/16)
Board Position:	Oppose Unless Amended (Ver. 4/30/15)

Assembly Bill 45 requires the California Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste and allows a local jurisdiction to adopt one of the model ordinances. Household hazardous waste, as defined, includes a variety of products, chemicals, electronics and other items –

including home-generated sharps waste as well as home-generated pharmaceutical waste. The Household Hazardous Waste Collection and Reduction plan defines home-generated pharmaceutical waste as prescription or nonprescription drugs, as specified in sections 4022 or 4025.1 of the Business and Professions Code, except that it shall not include any drug for which a producer provides a take-back program as part of a US FDA managed risk evaluation and mitigation strategy, as defined.

The comprehensive programs may include, but are not limited to

(1) Utilization of locally sponsored collection sites
(2) Scheduled and publicly advertised drop-off days
(3) Door-to-door collection programs
(4) Mobile collection programs
(5) Dissemination of information about how consumers should dispose of the various types of household hazardous waste, and
(6) Education programs to promote consumer understanding and use of the local components of a comprehensive program.

For prior versions of the bill, board staff has offered amendments to require the use of mail-back programs for home-generated pharmaceutical waste unless the jurisdiction complies with the provisions of federal law relating to the safe collection and disposal of such waste; the board's requested amendments have been rejected. A copy of AB 45 as well as the author's fact sheet is provided in Attachment 1.

2. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

Last Amend:	July 1, 2015
Coauthors:	Senators Beall and Wieckowski; Assemblymembers Chu, Low and Mark Stone
Status:	In Senate Appropriations (as of 8/17/15)
Board Position:	Oppose Unless Amended

AB 1069 would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Board staff has worked with the author's office to secure amendments to address many of the legal conflicts the measure initially contained, but there are still some concerns with the bill in its current form. Currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a "participating entity" to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources … all to the detriment of patient safety. Staff will continue to work with the

author's office on this measure and will provide an update on this bill – if any is available – at the board meeting. A copy of AB 1069 is provided in Attachment 1.

3. AB 1386 (Low) Epinephrine Auto-Injectors
   Last Amend: January 13, 2016
   Coauthors: Assemblymembers Chang, Daly and Wilk, and Senator Huff
   Status: Double referred: Senate Health and Senate Judiciary
   Board Position: None

   This measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a health care provider to issue a prescription, and a pharmacy to furnish epinephrine auto-injectors to an authorized *entity,* as defined. The bill calls for specific labeling on any epinephrine auto-injectors dispensed pursuant to the bill's provisions. Authorized entities include 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 defined. As is with current law, authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors shall be established and approved by the California Emergency Medical Services Authority (EMSA). A copy of the bill is provided in Attachment 1.

c. Legislation Impacting Board Operations

ATTACHMENT 2

1. AB 12 (Cooley) State Government: Administrative Regulations
   Last Amend: August 19, 2015
   Coauthors: Assemblymembers Chang, Daly and Wilk, and Senator Huff
   Status: Senate Appropriations (Held under submission - 8/27/15)
   Board Position: Oppose (October 2015)

   Assembly Bill 12 would require state agencies and departments to review, adopt, amend, or repeal any application regulations that are duplicative, overlapping, inconsistent, or out of date by January 1, 2018. The measure also would establish notice and reporting requirements.

   The board has determined that AB 12 would have a significant impact to its current operations. Given the complexity of the board's regulatory structure, board staff has concerns that the board would not be able to achieve compliance within the time allotted for completion of the review (2 years), without having a significant impact on other areas of the board's operations. A copy of AB 12 is provided in Attachment 2.

2. SB 952 (Anderson) Pharmacy Technician Licensure Requirements
Status: Introduced February 4, 2016 – To Rules for Assignment (as of 2/5/16)

For several months, the Licensing Committee and the board has been discussing Pharmacy Technician licensure requirements and duties. The discussion also is a part of this month's Board Meeting. As summarized by the Licensing Committee chair, the committee heard in January 2016 a presentation from the National Healthcareer Association (NHA) which administers the Exam for the Certification of Pharmacy Technicians (ExCPT).

Current law specifies that the board may issue a pharmacy technician license to an individual that meets specified educational requirements – one of which is certification by the Pharmacy Technician Certification Board.

The National Healthcareer Association is sponsoring Senate Bill 952 to amend section 4202 to modify the PTCB requirement. Specifically, to state that the individual 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."*

A copy of SB 952 is provided in Attachment 2. The bill can be acted upon on or after March 6 once referred to a policy committee. Staff will provide an analysis at the board meeting.

d. Implementation of Assembly Bill 15 (Chapter 1, Statutes of 2015-16 Second Extraordinary Session) End of Life Option Act

On October 5, 2015, Governor Brown signed the End of Life Option Act (Act). The provisions will take effect 90 days following the end of the second special legislative session (which is ongoing at the time this section was written). A copy of Chapter 1, Statutes of 2015-16 Second Extraordinary Session, is provided in Attachment 3.

This law allows a Californian with a terminal illness and who complies with specified criteria to end his or her life through the voluntary self-administration of lethal medications, expressly prescribed by a physician for that purpose. The law is very specific and contains procedures that physicians, pharmacies and patients need to follow. There are no exceptions to the requirements specified in the law.

Very generally, to qualify for a prescription for medication under the End of Life Option Act, a patient must be:

- A resident of California (specific qualifying criteria are provided in the law);
- 18 years of age or older;

- Mentally competent, i.e., capable of making and communicating your health care decisions; and
- Diagnosed with a terminal illness that will, within reasonable medical judgment, lead to death within six months.

The patient must be able to self-administer and ingest the prescribed medication. Two physicians must determine whether all these criteria have been met.

The attending physician, if he or she possesses specified criteria and with the consent of the qualified individual (the patient), may contact a pharmacist, informing the pharmacist of the prescriptions and delivering to the pharmacist the written prescriptions personally, by mail or electronically. The pharmacist may dispense the drug to the qualified individual, the attending physician or a person expressly designated by the qualified individual and with the designation delivered to the pharmacist in writing or verbally.

The law requires that a specified request form for an aid-in-dying drug include, among other things, the following statement:

> *I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.*

The law also requires that a person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to the Act after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or – if none is available – the person shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program.

e. Other Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

ATTACHMENT 4

1. AB 1306 (Burke) Healing Arts, Certified Nurse-Midwives: Scope of Practice

   Last Amend: July 1, 2015
   Coauthors: Assemblymember Mark Stone
   Status: Senate Business, Professions and Economic Development (last heard in July 2015)
   Board Position: None

   Assembly Bill 1306 addresses the scope of practice for certified nurse-midwives. The bill also creates and appoints a Nurse-Midwifery Advisory Council.

Current Pharmacy law (sections 4061 and 4076) restricts the distribution of dangerous drugs or dangerous devices to a physician, dentist, podiatrist, optometrist, veterinarian or naturopathic doctor, except where the certified nurse-midwife functions pursuant to a standardized procedure or protocol and where the drug or device has been identified in the standard procedure, protocol or practice agreement. A similar 'protocol' provision currently applies to a nurse practitioner, a physician assistant or a naturopathic doctor.

Assembly Bill 1306 deletes the references in Pharmacy Law to the standardized procedures and protocols and supervision for the furnishing of drugs and devices for a certified nurse-midwife. The bill authorizes a certified nurse-midwife to furnish or order drugs or devices related to the care they render in a home setting, as specified. A copy of the bill is provided in Attachment 4.

Part 2: REGULATION REPORT

a. Newly Effective Regulations

ATTACHMENT 5

1. Regulations to Add Title 16 CCR section 1746.2 Related to Nicotine Replacement Products

   On January 25, 2016, the Office of Administrative Law approved the board's rulemaking to add Section 1746.2 to Title 16 of the California Code of Regulations related to Nicotine Replacement Products. On February 2, 2016, the board issued a Subscriber Alert announcing that pharmacies can furnish nicotine replacement therapy (NRT) to assist patients in smoking cessation. Attachment 5 contains a copy of the adopted language which went into effect on January 25, 2016, as well as a copy of the board's Subscriber Alert.

2. Regulations to Add Title 16 CCR section 1746.3 Related to Naloxone Hydrochloride (Non-Emergency Adoption)

   In April 2015, the board initiated a rulemaking to establish a regulation to set forth requirements that a pharmacist must follow to furnish Naloxone Hydrochloride without a doctor's prescription. This 'regular' rulemaking was initiated following the adoption of an emergency regulation that first went into effect on April 10, 2015. The regulation text was adopted by the board in September, and the formal review process began in October. On January 27, 2016, the Office of Administrative Law approved the regulation to add Section 1746.2 to Title 16 of the California Code of Regulations, and filed it with the Secretary of State. The regulation went into effect on January 27, 2016.

A copy of the approved regulation language as well as the Subscriber Alert sent by the board is provided in Attachment 5.

a. Board Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law

ATTACHMENT 6

1. Proposed Regulation to Add Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception

In May 2015, the board initiated a formal rulemaking to add Section 1746.1 to Title 16 California Code of Regulations to establish a protocol for pharmacists to follow to furnish self-administered hormonal contraception without a doctor's prescription. On January 19, 2016, following the completion of a 45-day comment period and a 15-day comment period, the board approved the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law on January 21, 2016 for final review. A copy of the approved regulation language is provided in Attachment 6.

2. Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14, and 17M-26

In March 2015, the board initiated a formal rulemaking process to amend the text of Title 16 California Code of Regulations Sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference therein. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s).

Following the completion of two 45-day comment periods, the board approved the final regulation text on January 19, 2016. The final rulemaking file was submitted to the Department of Consumer Affairs on February 4, 2016 for final review. A copy of the approved regulation language is provided in Attachment 6.

3. Proposal to Add Title 16 CCR section 1746.4 related to Vaccinations

In July 2015, the board initiated a formal rulemaking to add Section 1746.4 to Title 16 California Code of Regulations to set forth requirements for pharmacists to follow or initiate and/or administer vaccinations without a doctor's prescription for persons three (3) years of age or older. The rulemaking is necessary to carry out the purpose of Section 4052(a)(11) and 4052.8 of the Business and Professions Code. Having pharmacists initiate and/or administer vaccinations will improve public health via greater public access to vaccinations. On January 19, 2016, following the completion of a 45-day comment

period and two 15-day comment periods, the board approved the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs on January 29, 2016 for final review. A copy of the approved regulation language is provided in Attachment 6.

b. Board Approved – Rulemaking File Being Prepared by Staff for Submission to the Department of Consumer Affairs and the Office of Administrative Law

ATTACHMENT 7

Proposal to Add Title 16 CCR section 1730 Related to Advanced Practice Pharmacist

In July 2015, staff initiated a formal rulemaking to add Section 1730 to Title 16 of the California Code of Regulations to set out specific requirements for the type of training, documentation, and fees needed to be paid to obtain an Advanced Practice Pharmacist (APP) license. The provisions allow a pharmacist with an APP license to perform physical assessments, order and interpret drug therapy-related tests, refer patients to other health care providers, and initiate, adjust, and discontinue drug therapies and evaluate and manage diseases and health conditions in collaboration with other health care providers. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board approved the final regulation text. Board staff is currently compiling the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law.

A copy of the approved regulation language is provided in Attachment 7.

c. Board Approved – Awaiting Notice

ATTACHMENT 8

1. Proposed Regulations to Amend Title 16 CCR section 1703 Related to "Section 100" requirements

At this meeting, the board will review proposed text to amend Section 1703 of Title 16 of the California Code of Regulations related to "Section 100" regulation changes – which would delegate to the Executive Officer the authority to initiate a rulemaking to adopt "changes without regulatory effect." The board first approved this text in 2013 and will re-review it at this meeting.

A copy of the board-approved language (not yet noticed) is provided in Attachment 8.

2. Proposed Regulations to Amend Title 16 CCR section 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements.

In 2013, the board approved proposed text to amend Sections 1702, 1702.1, 1702.2, and 1702.5 of Title 16 of the California Code of Regulations related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal. Board staff is preparing the required notice documents.

A copy of the board-approved language (not yet noticed) is provided in Attachment 8.

3. Proposed Regulations to Amend and/or Add Title 16 CCR sections 1780 – 1786 Related to Third-Party Logistics Providers

At the July 2015 Board Meeting, the board approved proposed text to amend and/or add Sections 1780 et seq. to Title 16 of the California Code of Regulations to establish regulatory requirements for Third-Party Logistics Providers. Board staff is preparing the required notice documents.

A copy of the board-approved language (not yet noticed) is provided in Attachment 8.

Attachment 1

AMENDED IN ASSEMBLY JANUARY 21, 2016

AMENDED IN ASSEMBLY APRIL 30, 2015

AMENDED IN ASSEMBLY APRIL 23, 2015

AMENDED IN ASSEMBLY APRIL 13, 2015

AMENDED IN ASSEMBLY MARCH 19, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 45

Introduced by Assembly Member Mullin

December 1, 2014

An act to add *and repeal* Article 3.4 (commencing with Section 47120) ~~to~~ *of* Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 45, as amended, Mullin. Household hazardous waste.

The California Integrated Waste Management Act of 1989, which is administered by the Department of Resources Recycling and Recovery, requires, among other things, each city and each county to prepare a household hazardous waste element containing specified components, and to submit that element to the department for approval. Existing law requires the department to approve the element if the local agency demonstrates that it will comply with specified requirements. A city or county is required to submit an annual report to the department summarizing its progress in reducing solid waste, including an update of the jurisdiction's household hazardous waste element.

~~This bill would require each jurisdiction that provides for the residential collection and disposal of solid waste to increase the collection and diversion of household hazardous waste in its service area, on or before July 1, 2020, by 15% over a baseline amount, to be determined in accordance with department regulations. The bill would authorize the department to adopt a model ordinance for a comprehensive program for the collection of household hazardous waste to facilitate compliance with those provisions, and would require each jurisdiction to annually report to the department on progress achieved in complying with those provisions. By imposing new duties on local agencies, the bill would impose a state-mandated local program.~~

~~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.~~

This bill would require the department to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste and would authorize a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance governing the collection and diversion of household hazardous waste to adopt one of the model ordinances adopted by the department. The bill would require the department to determine whether a nonprofit organization has been created and funded to make grants to local jurisdictions for specified purposes relating to household hazardous waste disposal and would specify that if the department does not determine that such a nonprofit organization exists by December 31, 2018, then the bill's provisions would be repealed on January 1, 2019.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~yes~~ *no*.

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

SECTION 1. ~~(a)~~ The Legislature finds and declares all of the following:

~~(1)~~

(a) Household hazardous waste is creating environmental, health, and workplace safety issues. Whether due to unused pharmaceuticals, batteries, medical devices, or other disposable

consumer items, effective and efficient disposal remains an extraordinary challenge.

~~(2)~~

(b) State and local efforts to address disposal of these items have been well intended and, in some cases, effective. However, even the most effective programs have very low consumer participation. Other approaches being promoted throughout the state would fragment the collection of household hazardous waste and move collection away from consumer convenience.

~~(3)~~

(c) In addition to other programs for the collection of household hazardous waste, a number of cities in California are already using curbside household hazardous waste collection programs, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services as mechanisms for collecting and disposing of many commonly used household items for which disposal has been the subject of state legislation ~~or~~ *and* local ordinances. The waste disposal companies and local governments that have implemented these programs have found them to be valuable components of a comprehensive approach to the management of household hazardous waste.

~~(4)~~

(d) There is also an appropriate role for manufacturers and distributors of these products in comprehensive efforts to more effectively manage household hazardous waste. That role should be based on the ability of manufacturers and distributors to communicate with consumers.

~~(b) It is the intent of the Legislature to enact legislation that would establish curbside household hazardous waste collection programs, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services as the principal means of collecting household hazardous waste and diverting it from California's landfills and waterways.~~

SEC. 2. Article 3.4 (commencing with Section 47120) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:

Article 3.4. Household Hazardous Waste Collection and Reduction

47120. For purposes of this article, the following terms have the following meanings:

(a) "Comprehensive program for the collection of household hazardous waste" means a local program that may include, but is not limited to, the following components:

(1) Utilization of locally sponsored collection sites.

(2) Scheduled and publicly advertised ~~drop off~~ *drop-off* days.

(3) Door-to-door collection programs.

(4) Mobile collection programs.

(5) Dissemination of information about how consumers should dispose of the various types of household hazardous waste.

(6) Education programs to promote consumer understanding and use of the local components of a comprehensive program.

(b) "Household hazardous waste" includes, but is not limited to, the following:

(1) Automotive products, including, but not limited to, antifreeze, batteries, brake fluid, motor oil, oil filters, fuels, wax, and polish.

(2) Garden chemicals, including, but not limited to, fertilizers, herbicides, insect sprays, pesticides, and weed killers.

(3) Household chemicals, including, but not limited to, ammonia, cleaners, strippers, and rust removers.

(4) Paint products, including, but not limited to, paint, caulk, glue, stripper, thinner, and wood preservatives and stain.

(5) Consumer electronics, including, but not limited to, televisions, computers, laptops, monitors, keyboards, DVD and CD players, VCRs, MP3 players, cell phones, desktop printers, scanners, fax machines, ~~mouses,~~ *computer mice*, microwaves, and related cords.

(6) Swimming pool chemicals, including, but not limited to, chlorine tablets and liquids, pool acids, and stabilizers.

(7) Household batteries. For purposes of this section, "household batteries" means batteries that individually weigh two kilograms or less of mercury, alkaline, carbon-zinc, or nickel-cadmium, and any other batteries typically generated as household waste, including, but not limited to, batteries used to provide power for consumer electronic and personal goods often found in a household.

(8) Fluorescent tubes and compact ~~florescent~~ *fluorescent* lamps.

(9) Mercury-containing items, including, but not limited to, thermometers, thermostats, and switches.

(10) Home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code.

(11) Home-generated pharmaceutical waste. For purposes of this section, "home-generated pharmaceutical waste" means a prescription or nonprescription drug, as specified in Section 4022 or 4025.1 of the Business and Professions Code, that is a waste generated by a household or households. "Home-generated pharmaceutical waste" shall not include drugs for which producers provide a take-back program as a part of a United States Food and Drug ~~Administration managed~~ *Administration-managed* risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, or waste generated by a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and a retailer.

~~47121. (a) (1) On or before July 1, 2020, each jurisdiction shall increase its collection and diversion of household hazardous waste in its service area by 15 percent over its baseline amount, as established pursuant to subdivision (b).~~

~~(2) Notwithstanding paragraph (1), a jurisdiction that has in place or adopts an ordinance implementing a comprehensive program for the collection of household hazardous waste shall have an additional two years to meet the collection and diversion objective in paragraph (1).~~

~~(b) No later than July 1, 2016, each jurisdiction shall inform the department of its baseline amount of collection and diversion of hazardous waste in accordance with regulations adopted by the department. The baseline amount may be expressed in tonnage or by the number of households participating, and may focus on particular types of household hazardous waste.~~

~~47122. (a) The department shall adopt regulations to implement this article.~~

~~(b) The department may adopt a model ordinance for a comprehensive program for the collection of household hazardous waste to facilitate compliance with this article.~~

~~47123. Commencing July 1, 2020, and annually thereafter, each jurisdiction shall report to the department on progress achieved in complying with this section. A jurisdiction shall make~~

~~a good faith effort to comply with this section, and the department may determine whether a jurisdiction has made a good faith effort for purposes of this program. To the maximum extent practicable, it is the intent of the Legislature that reporting requirements under this section be satisfied by submission of similar reports currently required by law.~~

~~47124. This article does not apply to a jurisdiction that does not provide for the residential collection and disposal of solid waste.~~

47121. (a) The department, in consultation with affected industries and stakeholders, shall adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste for adoption by any local jurisdiction that provides for the residential collection and disposal of solid waste.

(b) Upon adoption of the model ordinance or ordinances by the department, the department shall notify the public by posting the model ordinance or ordinances on the department's Internet Web site.

(c) After the department posts the model ordinance or ordinances on its Internet Web site, a local jurisdiction that proposes to enact an ordinance governing the collection and diversion of household hazardous waste may adopt one of the department's model ordinances.

47122. (a) The department shall determine whether an appropriate nonprofit organization has been created and funded for the purpose of making grants to local governments to assist with both of the following activities:

(1) Educating residents of communities on the existence of household hazardous waste disposal programs and how to use them.

(2) Defraying the cost of components of local government household hazardous waste programs.

(b) In making the determination set forth in subdivision (a), the department shall take all of the following into consideration:

(1) Whether the nonprofit organization has, at the time of the determination, a minimum of five million dollars ($5,000,000) dedicated to grants to local governments for the purposes set forth in subdivision (a).

(2) Whether the nonprofit organization will have sufficient funding to allocate grants to local governments throughout the state for five years.

(3) Whether the composition of the nonprofit's board of directors is sufficiently diverse and experienced to appropriately consider grant applications that will positively impact efforts to improve disposal of household hazardous waste.

(4) Whether the nonprofit organization has appropriate criteria for considering grant applications.

(c) Upon making a determination that an appropriate nonprofit organization exists as set forth in subdivision (a), the department shall post the fact that the department has made this determination on the department's Internet Web site.

47123. This article is applicable only to local jurisdictions that provide for the residential collection and disposal of solid waste.

47124. If the department does not make the determination that there exists an appropriate nonprofit organization, as specified in subdivision (a) of Section 47122, by December 31, 2018, this article shall be repealed on January 1, 2019.

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because a local agency or school district has the authority to levy service charges, fees, or assessments sufficient to pay for the program or level of service mandated by this act, within the meaning of Section 17556 of the Government Code.~~

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SUMMARY

Household Hazardous Wastes (HHW) are products individuals use in our daily lives that contain potentially hazardous ingredients. These products require special care when disposed of but more often than not consumers may not have the most convenient mechanisms to do so.

Although it is illegal to dispose of HHW in the trash, down the drain or by abandonment, people may not know the hazardous effects of these products on human health, animals and the environment.

Recent CalRecycle statistics indicate the State's HHW collection and disposal programs are moribund. Data shows that only 7% of Californians dispose of HHW products properly. This paltry participation rate shows how much improvement the state can make in the future.

CURRENT LAW

State law has loosely regulated Household Hazardous Wastes for approximately 25 years. Generally, HHWs are ubiquitous household products that contain small amounts of hazardous or toxic substances and require more intensive handling, treatment, or disposal than solid waste, but fall outside the State's hazardous waste laws applicable to industrial and large commercial facilities. HHWs include: paint, pesticides, compact fluorescent lamps (CFLs), batteries, sharps, discarded drugs, and similar products.

SOLUTION

AB 45 aims to coordinate with local governments, producers of HHW products and CalRecycle to adopt model ordinances for a comprehensive program for the collection of household hazardous waste.

Local governments have the option to choose whether or not to use the model ordinances listed by CalRecycle.

In addition, CalRecycle will determine whether or not an appropriate nonprofit organization has been created with the following considerations:

1) has a minimum of 5 million dollars dedicated to assist in educating residents about HHW disposal programs and how to use them (please see attached industry letter)

2) has sufficient funding to allocate grants to local governments throughout the state

3) the board of directors is diverse and experienced to appropriately consider grant applications that will positively impact efforts to improve disposal of HHW

4) has appropriate criteria for considering grant applications

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AMENDED IN SENATE JULY 1, 2015

AMENDED IN ASSEMBLY MAY 6, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1069

Introduced by Assembly Member Gordon
(Coauthors: Assembly Members Chu, Low, and Mark Stone)
(Coauthors: Senators Beall and Wieckowski)

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as amended, 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. Existing law requires a county that establishes a depository and redistribution program to develop written procedures for, among other things, establishing eligibility for medically indigent patients who may participate in the program, and ensuring that patients eligible for the program are not charged for any medications provided under the program. Existing law also prohibits the donation of controlled substances to the repository and distribution program. 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 authorizes a county-owned pharmacy participating in the program to transfer eligible donated medication to a county-owned pharmacy participating in the program within another adjacent county, as specified. 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 county-owned pharmacy~~ *an entity* participating in the medication repository and distribution program to transfer eligible donated medication to a participating ~~county-owned pharmacy~~ *entity* in any other county, as specified. *The bill would generally prohibit an entity from transferring more than 15% of its donated medications annually.* The bill would authorize medication donated to a medication repository and distribution program to be maintained in new, properly labeled ~~containers.~~ *containers, as specified.* The bill would prohibit donated medication from being repackaged more than 2 times. This bill would also make a technical, nonsubstantive change to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

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~~ *entity* may transfer eligible donated medication to a participating ~~county-owned pharmacy~~ *entity* within another county that has adopted a program pursuant to this division, if the ~~pharmacies~~ *participating entities* 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. *A participating entity shall not transfer more than 15 percent of its donated medications annually unless the transfer is performed pursuant to Section 4126.5 of the Business and Professions Code.*

(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)* Medication donated to the repository and distribution program shall be maintained in the donated packaging units or new, properly labeled containers 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. Donated medication shall not be repackaged more than two times. Nothing in this section requires donated medication to be repackaged two times.

(2) All of the following requirements shall be satisfied when repackaging donated medication:

(A) Medication shall be repackaged into a container that holds an individual prescription for a supply of no more than 90 days.

(B) Repackaged medication shall be identifiable as donated medication.

(C) Repackaged medication shall be labeled with all of the following:

(i) All applicable lot numbers.

(ii) The earliest expiration date.

(iii) The number of times that the medication has been repackaged.

(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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AMENDED IN ASSEMBLY JANUARY 13, 2016

AMENDED IN ASSEMBLY JANUARY 5, 2016

AMENDED IN ASSEMBLY JANUARY 4, 2016

AMENDED IN ASSEMBLY APRIL 16, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1386

Introduced by Assembly Member Low

February 27, 2015

An act to add Section 4119.4 to the Business and Professions Code, to amend Section 1714.23 of the Civil Code, and to amend Section 1797.197a of the Health and Safety Code, relating to emergency medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 1386, as amended, 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,~~ *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.

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 pursuant to those provisions.~~ *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 State Department of Public Health on incidents related to the administration of epinephrine auto-injectors. The bill would also require the department to issue an annual report summarizing and analyzing the reports submitted to the department pursuant to the bill's provisions.

(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 ~~any employee, agent, or other trained individual of an authorized entity 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. The bill would also 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.

(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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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, as defined by 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 ~~the possession of an authorized entity and for use by its employees, volunteers, and agents, first responder, or by a family member or caregiver of the person who appears to be experiencing anaphylaxis, as defined by paragraph (1) of subdivision (a) of Section 1714.23 of the Civil Code, or by the person who appears to be experiencing anaphylaxis, as defined by paragraph (1) of subdivision (a) of Section 1714.23 of the Civil Code.~~ *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.

(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.

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 drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(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) An authorized health care provider that prescribes or dispenses an epinephrine auto-injector to a person described in subdivision (b) of Section 1797.197a of the Health and Safety Code or an authorized entity is not liable for any civil damages resulting from any act or omission related to the provision of an epinephrine auto-injector.~~

~~(3) A person that conducts the training described in subdivision (c) of Section 1797.197a of the Health and Safety Code is not~~

~~liable for any civil damages resulting from any act or omission of the lay rescuer, as defined by paragraph (4) of subdivision (a) of Section 1797.197a of the Health and Safety Code, who renders emergency care by administering the epinephrine auto-injector.~~

~~(4)~~

(2) (A) An authorized entity shall not be ~~liable,~~ *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, or who, in good faith, and not for compensation, renders emergency medical or nonmedical care at the scene of an emergency.~~ *Code.*

(B) The failure of an authorized entity to possess or administer an epinephrine auto-injector shall not result in civil liability.

~~(5)~~

(3) This subdivision does not affect any other immunity or defense that is available under ~~law, including, but not limited to, the immunity from liability for any civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct of a person who in good faith, and not for compensation, renders emergency medical or nonmedical care at the scene of an emergency as provided by section 1799.102 of the Health and Safety Code.~~ *law.*

(c) The protection specified in 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.

SEC. 3. 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 drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(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). ~~An authorized health care provider may issue a prescription for an epinephrine auto-injector to a person described in this subdivision for the purpose of rendering emergency care to another person, upon presentation of current certification demonstrating that person is trained and qualified to administer an epinephrine auto-injector as a prehospital emergency medical care person or lay rescuer, pursuant to this section or any other statute or regulation.~~

(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) An authorized health care provider may prescribe epinephrine auto-injectors to an authorized entity. Epinephrine auto-injectors acquired by an authorized entity shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injectors instructions for use and any additional requirements that may be established by the authority.~~

(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 certification 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 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.~~ *auto-injector or used epinephrine auto-injector in a sharps container.*

(2) Submit to the State Department of Public Health, on a form developed by the State Department of Public Health, a report of each incident on the authorized entity's premises that involves the administration of an epinephrine auto-injector. The State Department of Public Health shall annually publish a report that summarizes and analyzes 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. 4. 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

AMENDED IN SENATE AUGUST 19, 2015

AMENDED IN ASSEMBLY APRIL 22, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 12

Introduced by Assembly Member Cooley
(Coauthors: Assembly Members Chang, Daly, and Wilk)
(Coauthor: Senator Huff)

December 1, 2014

An act to add and repeal Chapter 3.6 (commencing with Section 11366) of Part 1 of Division 3 of Title 2 of the Government Code, relating to state agency regulations.

LEGISLATIVE COUNSEL'S DIGEST

AB 12, as amended, Cooley. State government: administrative regulations: review.

Existing law authorizes various state entities to adopt, amend, or repeal regulations for various specified purposes. The Administrative Procedure Act requires the Office of Administrative Law and a state agency proposing to adopt, amend, or repeal a regulation to review the proposed changes for, among other things, consistency with existing state regulations.

This bill would, until January 1, 2019, require each state agency to, on or before January 1, 2018, review that agency's regulations, identify any regulations that are duplicative, overlapping, inconsistent, or out of date, to revise those identified regulations, as provided, and report to the Legislature and Governor, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Chapter 3.6 (commencing with Section 11366) is added to Part 1 of Division 3 of Title 2 of the Government Code, to read:

Chapter 3.6. Regulatory Reform

Article 1. Findings and Declarations

11366. The Legislature finds and declares all of the following:

(a) The Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500)) requires agencies and the Office of Administrative Law to review regulations to ensure their consistency with law and to consider impacts on the state's economy and businesses, including small businesses.

(b) However, the act does not require agencies to individually review their regulations to identify overlapping, inconsistent, duplicative, or out-of-date regulations that may exist.

(c) At a time when the state's economy is slowly recovering, unemployment and underemployment continue to affect all Californians, especially older workers and younger workers who received college degrees in the last seven years but are still awaiting their first great job, and with state government improving but in need of continued fiscal discipline, it is important that state agencies systematically undertake to identify, publicly review, and eliminate overlapping, inconsistent, duplicative, or out-of-date regulations, both to ensure they more efficiently implement and enforce laws and to reduce unnecessary and outdated rules and regulations.

Article 2. Definitions

11366.1. For the purposes of this chapter, the following definitions shall apply:

(a) "State agency" means a state agency, as defined in Section 11000, except those state agencies or activities described in Section 11340.9.

(b) "Regulation" has the same meaning as provided in Section 11342.600.

Article 3. State Agency Duties

11366.2. On or before January 1, 2018, each state agency shall do all of the following:

(a) Review all provisions of the California Code of Regulations ~~applicable to, or adopted by,~~ *adopted by* that state agency.

(b) Identify any regulations that are duplicative, overlapping, inconsistent, or out of date.

(c) Adopt, amend, or repeal regulations to reconcile or eliminate any duplication, overlap, inconsistencies, or out-of-date provisions, and shall comply with the process specified in Article 5 (commencing with Section 11346) of Chapter 3.5, unless the addition, revision, or deletion is without regulatory effect and may be done pursuant to Section 100 of Title 1 of the California Code of Regulations.

(d) Hold at least one noticed public hearing, ~~that~~ *which* shall be noticed on the Internet Web site of the state agency, for the purposes of accepting public comment on proposed revisions to its regulations.

(e) Notify the appropriate policy and fiscal committees of each house of the Legislature of the revisions to regulations that the state agency proposes to make at least 30 days prior to initiating the process under Article 5 (commencing with Section 11346) of Chapter 3.5 or Section 100 of Title 1 of the California Code of Regulations.

(g) (1) Report to the Governor and the Legislature on the state agency's compliance with this chapter, including the number and content of regulations the state agency identifies as duplicative, overlapping, inconsistent, or out of date, and the state agency's actions to address those regulations.

(2) The report shall be submitted in compliance with Section 9795 of the Government Code.

11366.3. (a) On or before January 1, 2018, each agency listed in Section 12800 shall notify a department, board, or other unit within that agency of any existing regulations adopted by that department, board, or other unit that the agency has determined may be duplicative, overlapping, or inconsistent with a regulation

adopted by another department, board, or other unit within that agency.

(b) A department, board, or other unit within an agency shall notify that agency of revisions to regulations that it proposes to make at least 90 days prior to a noticed public hearing pursuant to subdivision (d) of Section 11366.2 and at least 90 days prior to adoption, amendment, or repeal of the regulations pursuant to subdivision (c) of Section 11366.2. The agency shall review the proposed regulations and make recommendations to the department, board, or other unit within 30 days of receiving the notification regarding any duplicative, overlapping, or inconsistent regulation of another department, board, or other unit within the agency.

11366.4. An agency listed in Section 12800 shall notify a state agency of any existing regulations adopted by that agency that may duplicate, overlap, or be inconsistent with the state agency's regulations.

11366.45. This chapter shall not be construed to weaken or undermine in any manner any human health, public or worker rights, public welfare, environmental, or other protection established under statute. This chapter shall not be construed to affect the authority or requirement for an agency to adopt regulations as provided by statute. Rather, it is the intent of the Legislature to ensure that state agencies focus more efficiently and directly on their duties as prescribed by law so as to use scarce public dollars more efficiently to implement the law, while achieving equal or improved economic and public benefits.

Article 4. Chapter Repeal

11366.5. This chapter shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.

O

SENATE BILL No. 952

Introduced by Senator Anderson

February 4, 2016

An act to amend Section 4202 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 952, as introduced, 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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 ~~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.

O

Attachment 3

Assembly Bill No. 15

CHAPTER 1

An act to add and repeal Part 1.85 (commencing with Section 443) of Division 1 of the Health and Safety Code, relating to end of life.

[Approved by Governor October 5, 2015. Filed with Secretary of State October 5, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 15, Eggman. End of life.

Existing law authorizes an adult to give an individual health care instruction and to appoint an attorney to make health care decisions for that individual in the event of his or her incapacity pursuant to a power of attorney for health care.

This bill, until January 1, 2026, would enact the End of Life Option Act authorizing an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease, as defined, to make a request for a drug prescribed pursuant to these provisions for the purpose of ending his or her life. The bill would establish the procedures for making these requests. The bill would also establish specified forms to request an aid-in-dying drug, under specified circumstances, an interpreter declaration to be signed subject to penalty of perjury, thereby creating a crime and imposing a state-mandated local program, and a final attestation for an aid-in-dying drug. This bill would require specified information to be documented in the individual's medical record, including, among other things, all oral and written requests for an aid-in-dying drug.

This bill would prohibit a provision in a contract, will, or other agreement from being conditioned upon, or affected by, a person making or rescinding a request for the above-described drug. The bill would prohibit the sale, procurement, or issuance of any life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged for any policy or plan contract, from being conditioned upon or affected by the request. The bill would prohibit an insurance carrier from providing any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. The bill would also prohibit any communication from containing both the denial of treatment and information as to the availability of aid-in-dying drug coverage.

This bill would provide a person, except as provided, immunity from civil or criminal liability solely because the person was present when the qualified individual self-administered the drug, or the person assisted the qualified individual by preparing the aid-in-dying drug so long as the person did not

assist with the ingestion of the drug, and would specify that the immunities and prohibitions on sanctions of a health care provider are solely reserved for conduct of a health care provider provided for by the bill. The bill would make participation in activities authorized pursuant to its provisions voluntary, and would make health care providers immune from liability for refusing to engage in activities authorized pursuant to its provisions. The bill would also authorize a health care provider to prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under the act while on the premises owned or under the management or direct control of that prohibiting health care provider, or while acting within the course and scope of any employment by, or contract with, the prohibiting health care provider.

This bill would make it a felony to knowingly alter or forge a request for drugs to end an individual's life without his or her authorization or to conceal or destroy a withdrawal or rescission of a request for a drug, if it is done with the intent or effect of causing the individual's death. The bill would make it a felony to knowingly coerce or exert undue influence on an individual to request a drug for the purpose of ending his or her life, to destroy a withdrawal or rescission of a request, or to administer an aid-in-dying drug to an individual without their knowledge or consent. By creating a new crime, the bill would impose a state-mandated local program. The bill would provide that nothing in its provisions is to be construed to authorize ending a patient's life by lethal injection, mercy killing, or active euthanasia, and would provide that action taken in accordance with the act shall not constitute, among other things, suicide or homicide.

This bill would require physicians to submit specified forms and information to the State Department of Public Health after writing a prescription for an aid-in-dying drug and after the death of an individual who requested an aid-in-dying drug. The bill would authorize the Medical Board of California to update those forms and would require the State Department of Public Health to publish the forms on its Internet Web site. The bill would require the department to annually review a sample of certain information and records, make a statistical report of the information collected, and post that report to its Internet Web site.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

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. Part 1.85 (commencing with Section 443) is added to Division 1 of the Health and Safety Code, to read:

PART 1.85. END OF LIFE OPTION ACT

443. This part shall be known and may be cited as the End of Life Option Act.

443.1. As used in this part, the following definitions shall apply:

(a) "Adult" means an individual 18 years of age or older.

(b) "Aid-in-dying drug" means a drug determined and prescribed by a physician for a qualified individual, which the qualified individual may choose to self-administer to bring about his or her death due to a terminal disease.

(c) "Attending physician" means the physician who has primary responsibility for the health care of an individual and treatment of the individual's terminal disease.

(d) "Attending physician checklist and compliance form" means a form, as described in Section 443.22, identifying each and every requirement that must be fulfilled by an attending physician to be in good faith compliance with this part should the attending physician choose to participate.

(e) "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make and communicate an informed decision to health care providers.

(f) "Consulting physician" means a physician who is independent from the attending physician and who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding an individual's terminal disease.

(g) "Department" means the State Department of Public Health.

(h) "Health care provider" or "provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of this code; and any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of this code.

(i) "Informed decision" means a decision by an individual with a terminal disease to request and obtain a prescription for a drug that the individual may self-administer to end the individual's life, that is based on an understanding and acknowledgment of the relevant facts, and that is made after being fully informed by the attending physician of all of the following:

(1) The individual's medical diagnosis and prognosis.

(2) The potential risks associated with taking the drug to be prescribed.

(3) The probable result of taking the drug to be prescribed.

(4) The possibility that the individual may choose not to obtain the drug or may obtain the drug but may decide not to ingest it.

(5) The feasible alternatives or additional treatment opportunities, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

(j) "Medically confirmed" means the medical diagnosis and prognosis of the attending physician has been confirmed by a consulting physician who has examined the individual and the individual's relevant medical records.

(k) "Mental health specialist assessment" means one or more consultations between an individual and a mental health specialist for the purpose of determining that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

(*l*) "Mental health specialist" means a psychiatrist or a licensed psychologist.

(m) "Physician" means a doctor of medicine or osteopathy currently licensed to practice medicine in this state.

(n) "Public place" means any street, alley, park, public building, any place of business or assembly open to or frequented by the public, and any other place that is open to the public view, or to which the public has access.

(o) "Qualified individual" means an adult who has the capacity to make medical decisions, is a resident of California, and has satisfied the requirements of this part in order to obtain a prescription for a drug to end his or her life.

(p) "Self-administer" means a qualified individual's affirmative, conscious, and physical act of administering and ingesting the aid-in-dying drug to bring about his or her own death.

(q) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six months.

443.2. (a) An individual who is an adult with the capacity to make medical decisions and with a terminal disease may make a request to receive a prescription for an aid-in-dying drug if all of the following conditions are satisfied:

(1) The individual's attending physician has diagnosed the individual with a terminal disease.

(2) The individual has voluntarily expressed the wish to receive a prescription for an aid-in-dying drug.

(3) The individual is a resident of California and is able to establish residency through any of the following means:

(A) Possession of a California driver license or other identification issued by the State of California.

(B) Registration to vote in California.

(C) Evidence that the person owns or leases property in California.

(D) Filing of a California tax return for the most recent tax year.

(4) The individual documents his or her request pursuant to the requirements set forth in Section 443.3.

(5) The individual has the physical and mental ability to self-administer the aid-in-dying drug.

(b) A person shall not be considered a "qualified individual" under the provisions of this part solely because of age or disability.

(c) A request for a prescription for an aid-in-dying drug under this part shall be made solely and directly by the individual diagnosed with the terminal disease and shall not be made on behalf of the patient, including, but not limited to, through a power of attorney, an advance health care directive, a conservator, health care agent, surrogate, or any other legally recognized health care decisionmaker.

443.3. (a) An individual seeking to obtain a prescription for an aid-in-dying drug pursuant to this part shall submit two oral requests, a minimum of 15 days apart, and a written request to his or her attending physician. The attending physician shall directly, and not through a designee, receive all three requests required pursuant to this section.

(b) A valid written request for an aid-in-dying drug under subdivision (a) shall meet all of the following conditions:

(1) The request shall be in the form described in Section 443.11.

(2) The request shall be signed and dated, in the presence of two witnesses, by the individual seeking the aid-in-dying drug.

(3) The request shall be witnessed by at least two other adult persons who, in the presence of the individual, shall attest that to the best of their knowledge and belief the individual is all of the following:

(A) An individual who is personally known to them or has provided proof of identity.

(B) An individual who voluntarily signed this request in their presence.

(C) An individual whom they believe to be of sound mind and not under duress, fraud, or undue influence.

(D) Not an individual for whom either of them is the attending physician, consulting physician, or mental health specialist.

(c) Only one of the two witnesses at the time the written request is signed may:

(1) Be related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the individual's estate upon death.

(2) Own, operate, or be employed at a health care facility where the individual is receiving medical treatment or resides.

(d) The attending physician, consulting physician, or mental health specialist of the individual shall not be one of the witnesses required pursuant to paragraph (3) of subdivision (b).

443.4. (a) An individual may at any time withdraw or rescind his or her request for an aid-in-dying drug, or decide not to ingest an aid-in-dying drug, without regard to the individual's mental state.

(b) A prescription for an aid-in-dying drug provided under this part may not be written without the attending physician directly, and not through a designee, offering the individual an opportunity to withdraw or rescind the request.

443.5. (a) Before prescribing an aid-in-dying drug, the attending physician shall do all of the following:

(1) Make the initial determination of all of the following:

(A) (i) Whether the requesting adult has the capacity to make medical decisions.

(ii) If there are indications of a mental disorder, the physician shall refer the individual for a mental health specialist assessment.

(iii) If a mental health specialist assessment referral is made, no aid-in-dying drugs shall be prescribed until the mental health specialist determines that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

(B) Whether the requesting adult has a terminal disease.

(C) Whether the requesting adult has voluntarily made the request for an aid-in-dying drug pursuant to Sections 443.2 and 443.3.

(D) Whether the requesting adult is a qualified individual pursuant to subdivision (o) of Section 443.1.

(2) Confirm that the individual is making an informed decision by discussing with him or her all of the following:

(A) His or her medical diagnosis and prognosis.

(B) The potential risks associated with ingesting the requested aid-in-dying drug.

(C) The probable result of ingesting the aid-in-dying drug.

(D) The possibility that he or she may choose to obtain the aid-in-dying drug but not take it.

(E) The feasible alternatives or additional treatment options, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

(3) Refer the individual to a consulting physician for medical confirmation of the diagnosis and prognosis, and for a determination that the individual has the capacity to make medical decisions and has complied with the provisions of this part.

(4) Confirm that the qualified individual's request does not arise from coercion or undue influence by another person by discussing with the qualified individual, outside of the presence of any other persons, except for an interpreter as required pursuant to this part, whether or not the qualified individual is feeling coerced or unduly influenced by another person.

(5) Counsel the qualified individual about the importance of all of the following:

(A) Having another person present when he or she ingests the aid-in-dying drug prescribed pursuant to this part.

(B) Not ingesting the aid-in-dying drug in a public place.

(C) Notifying the next of kin of his or her request for an aid-in-dying drug. A qualified individual who declines or is unable to notify next of kin shall not have his or her request denied for that reason.

(D) Participating in a hospice program.

(E) Maintaining the aid-in-dying drug in a safe and secure location until the time that the qualified individual will ingest it.

(6) Inform the individual that he or she may withdraw or rescind the request for an aid-in-dying drug at any time and in any manner.

(7) Offer the individual an opportunity to withdraw or rescind the request for an aid-in-dying drug before prescribing the aid-in-dying drug.

(8) Verify, immediately before writing the prescription for an aid-in-dying drug, that the qualified individual is making an informed decision.

(9) Confirm that all requirements are met and all appropriate steps are carried out in accordance with this part before writing a prescription for an aid-in-dying drug.

(10) Fulfill the record documentation required under Sections 443.8 and 443.19.

(11) Complete the attending physician checklist and compliance form, as described in Section 443.22, include it and the consulting physician compliance form in the individual's medical record, and submit both forms to the State Department of Public Health.

(12) Give the qualified individual the final attestation form, with the instruction that the form be filled out and executed by the qualified individual within 48 hours prior to the qualified individual choosing to self-administer the aid-in-dying drug.

(b) If the conditions set forth in subdivision (a) are satisfied, the attending physician may deliver the aid-in-dying drug in any of the following ways:

(1) Dispensing the aid-in-dying drug directly, including ancillary medication intended to minimize the qualified individual's discomfort, if the attending physician meets all of the following criteria:

(A) Is authorized to dispense medicine under California law.

(B) Has a current United States Drug Enforcement Administration (USDEA) certificate.

(C) Complies with any applicable administrative rule or regulation.

(2) With the qualified individual's written consent, contacting a pharmacist, informing the pharmacist of the prescriptions, and delivering the written prescriptions personally, by mail, or electronically to the pharmacist, who may dispense the drug to the qualified individual, the attending physician, or a person expressly designated by the qualified individual and with the designation delivered to the pharmacist in writing or verbally.

(c) Delivery of the dispensed drug to the qualified individual, the attending physician, or a person expressly designated by the qualified individual may be made by personal delivery, or, with a signature required on delivery, by United Parcel Service, United States Postal Service, Federal Express, or by messenger service.

443.6. Before a qualified individual obtains an aid-in-dying drug from the attending physician, the consulting physician shall perform all of the following:

(a) Examine the individual and his or her relevant medical records.

(b) Confirm in writing the attending physician's diagnosis and prognosis.

(c) Determine that the individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision.

(d) If there are indications of a mental disorder, refer the individual for a mental health specialist assessment.

(e) Fulfill the record documentation required under this part.

(f) Submit the compliance form to the attending physician.

443.7. Upon referral from the attending or consulting physician pursuant to this part, the mental health specialist shall:

(a) Examine the qualified individual and his or her relevant medical records.

(b) Determine that the individual has the mental capacity to make medical decisions, act voluntarily, and make an informed decision.

(c) Determine that the individual is not suffering from impaired judgment due to a mental disorder.

(d) Fulfill the record documentation requirements of this part.

443.8. All of the following shall be documented in the individual's medical record:

(a) All oral requests for aid-in-dying drugs.

(b) All written requests for aid-in-dying drugs.

(c) The attending physician's diagnosis and prognosis, and the determination that a qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the attending physician has determined that the individual is not a qualified individual.

(d) The consulting physician's diagnosis and prognosis, and verification that the qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the consulting physician has determined that the individual is not a qualified individual.

(e) A report of the outcome and determinations made during a mental health specialist's assessment, if performed.

(f) The attending physician's offer to the qualified individual to withdraw or rescind his or her request at the time of the individual's second oral request.

(g) A note by the attending physician indicating that all requirements under Sections 443.5 and 443.6 have been met and indicating the steps taken to carry out the request, including a notation of the aid-in-dying drug prescribed.

443.9. (a) Within 30 calendar days of writing a prescription for an aid-in-dying drug, the attending physician shall submit to the State Department of Public Health a copy of the qualifying patient's written request, the attending physician checklist and compliance form, and the consulting physician compliance form.

(b) Within 30 calendar days following the qualified individual's death from ingesting the aid-in-dying drug, or any other cause, the attending physician shall submit the attending physician followup form to the State Department of Public Health.

443.10. A qualified individual may not receive a prescription for an aid-in-dying drug pursuant to this part unless he or she has made an informed decision. Immediately before writing a prescription for an aid-in-dying drug under this part, the attending physician shall verify that the individual is making an informed decision.

443.11. (a) A request for an aid-in-dying drug as authorized by this part shall be in the following form:

REQUEST FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER I, ..., am an adult of sound mind and a resident of the State of California.

I am suffering from ....., which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.

INITIAL ONE:

..... I have informed one or more members of my family of my decision and taken their opinions into consideration.

..... I have decided not to inform my family of my decision.

..... I have no family to inform of my decision.

I understand that I have the right to withdraw or rescind this request at any time.

I understand the full import of this request and I expect to die if I take the aid-in-dying drug to be prescribed. My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this request voluntarily, without reservation, and without being coerced.

Signed:.....

Dated:.....

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) is personally known to us or has provided proof of identity;

(b) voluntarily signed this request in our presence;

(c) is an individual whom we believe to be of sound mind and not under duress, fraud, or undue influence; and

(d) is not an individual for whom either of us is the attending physician, consulting physician, or mental health specialist.
.....Witness 1/Date
.....Witness 2/Date
NOTE: Only one of the two witnesses may be a relative (by blood, marriage, registered domestic partnership, or adoption) of the person signing this request or be entitled to a portion of the person's estate upon death. Only one of the two witnesses may own, operate, or be employed at a health care facility where the person is a patient or resident.

(b) (1) The written language of the request shall be written in the same translated language as any conversations, consultations, or interpreted conversations or consultations between a patient and his or her attending or consulting physicians.

(2) Notwithstanding paragraph (1), the written request may be prepared in English even when the conversations or consultations or interpreted conversations or consultations were conducted in a language other than English if the English language form includes an attached interpreter's declaration that is signed under penalty of perjury. The interpreter's declaration shall state words to the effect that:

I, (INSERT NAME OF INTERPRETER), am fluent in English and (INSERT TARGET LANGUAGE).
On (insert date) at approximately (insert time), I read the "Request for an Aid-In-Dying Drug to End My Life" to (insert name of individual/patient) in (insert target language).
Mr./Ms. (insert name of patient/qualified individual) affirmed to me that he/she understood the content of this form and affirmed his/her desire to sign this form under his/her own power and volition and that the request to sign the form followed consultations with an attending and consulting physician.
I declare that I am fluent in English and (insert target language) and further declare under penalty of perjury that the foregoing is true and correct.
Executed at (insert city, county, and state) on this (insert day of month) of (insert month), (insert year).
X_____Interpreter signature
X_____Interpreter printed name
X_____Interpreter address

(3) An interpreter whose services are provided pursuant to paragraph (2) shall not be related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the person's estate upon death. An interpreter whose services are provided pursuant to paragraph (2) shall meet the standards promulgated by the California Healthcare Interpreting Association or the National Council on Interpreting in Health Care or other standards deemed acceptable by the department for health care providers in California.

(c) The final attestation form given by the attending physician to the qualified individual at the time the attending physician writes the prescription shall appear in the following form:

FINAL ATTESTATION FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER I, ..., am an adult of sound mind and a resident of the State of California.
I am suffering from ....., which my attending physician has determined is in its terminal phase and which has been medically confirmed.
I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.
I have received the aid-in-dying drug and am fully aware that this aid-in-dying drug will end my life in a humane and dignified manner.
INITIAL ONE:
..... I have informed one or more members of my family of my decision and taken their opinions into consideration.
..... I have decided not to inform my family of my decision.
..... I have no family to inform of my decision.
My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.
I make this decision to ingest the aid-in-dying drug to end my life in a humane and dignified manner. I understand I still may choose not to ingest the drug and by signing this form I am under no obligation to ingest the drug. I understand I may rescind this request at any time.

Signed:.....
Dated:.....
Time:.....

(1) Within 48 hours prior to the individual self-administering the aid-in-dying drug, the individual shall complete the final attestation form. If aid-in-dying medication is not returned or relinquished upon the patient's death as required in Section 443.20, the completed form shall be delivered

by the individual's health care provider, family member, or other representative to the attending physician to be included in the patient's medical record.

(2) Upon receiving the final attestation form the attending physician shall add this form to the medical records of the qualified individual.

443.12. (a) A provision in a contract, will, or other agreement executed on or after January 1, 2016, whether written or oral, to the extent the provision would affect whether a person may make, withdraw, or rescind a request for an aid-in-dying drug is not valid.

(b) An obligation owing under any contract executed on or after January 1, 2016, may not be conditioned or affected by a qualified individual making, withdrawing, or rescinding a request for an aid-in-dying drug.

443.13. (a) (1) The sale, procurement, or issuance of a life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged for a policy or plan contract may not be conditioned upon or affected by a person making or rescinding a request for an aid-in-dying drug.

(2) Pursuant to Section 443.18, death resulting from the self-administration of an aid-in-dying drug is not suicide, and therefore health and insurance coverage shall not be exempted on that basis.

(b) Notwithstanding any other law, a qualified individual's act of self-administering an aid-in-dying drug shall not have an effect upon a life, health, or annuity policy other than that of a natural death from the underlying disease.

(c) An insurance carrier shall not provide any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. Any communication shall not include both the denial of treatment and information as to the availability of aid-in-dying drug coverage. For the purposes of this subdivision, "insurance carrier" means a health care service plan as defined in Section 1345 of this code or a carrier of health insurance as defined in Section 106 of the Insurance Code.

443.14. (a) Notwithstanding any other law, a person shall not be subject to civil or criminal liability solely because the person was present when the qualified individual self-administers the prescribed aid-in-dying drug. A person who is present may, without civil or criminal liability, assist the qualified individual by preparing the aid-in-dying drug so long as the person does not assist the qualified person in ingesting the aid-in-dying drug.

(b) A health care provider or professional organization or association shall not subject an individual to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty for participating in good faith compliance with this part or for refusing to participate in accordance with subdivision (e).

(c) Notwithstanding any other law, a health care provider shall not be subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff

action, sanction, or penalty or other liability for participating in this part, including, but not limited to, determining the diagnosis or prognosis of an individual, determining the capacity of an individual for purposes of qualifying for the act, providing information to an individual regarding this part, and providing a referral to a physician who participates in this part. Nothing in this subdivision shall be construed to limit the application of, or provide immunity from, Section 443.16 or 443.17.

(d) (1) A request by a qualified individual to an attending physician to provide an aid-in-dying drug in good faith compliance with the provisions of this part shall not provide the sole basis for the appointment of a guardian or conservator.

(2) No actions taken in compliance with the provisions of this part shall constitute or provide the basis for any claim of neglect or elder abuse for any purpose of law.

(e) (1) Participation in activities authorized pursuant to this part shall be voluntary. Notwithstanding Sections 442 to 442.7, inclusive, a person or entity that elects, for reasons of conscience, morality, or ethics, not to engage in activities authorized pursuant to this part is not required to take any action in support of an individual's decision under this part.

(2) Notwithstanding any other law, a health care provider is not subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff action, sanction, or penalty or other liability for refusing to participate in activities authorized under this part, including, but not limited to, refusing to inform a patient regarding his or her rights under this part, and not referring an individual to a physician who participates in activities authorized under this part.

(3) If a health care provider is unable or unwilling to carry out a qualified individual's request under this part and the qualified individual transfers care to a new health care provider, the individual may request a copy of his or her medical records pursuant to law.

443.15. (a) Subject to subdivision (b), notwithstanding any other law, a health care provider may prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under this part while on premises owned or under the management or direct control of that prohibiting health care provider or while acting within the course and scope of any employment by, or contract with, the prohibiting health care provider.

(b) A health care provider that elects to prohibit its employees, independent contractors, or other persons or entities, including health care providers, from participating in activities under this part, as described in subdivision (a), shall first give notice of the policy prohibiting participation under this part to the individual or entity. A health care provider that fails to provide notice to an individual or entity in compliance with this subdivision shall not be entitled to enforce such a policy against that individual or entity.

(c) Subject to compliance with subdivision (b), the prohibiting health care provider may take action, including, but not limited to, the following, as applicable, against any individual or entity that violates this policy:

(1) Loss of privileges, loss of membership, or other action authorized by the bylaws or rules and regulations of the medical staff.

(2) Suspension, loss of employment, or other action authorized by the policies and practices of the prohibiting health care provider.

(3) Termination of any lease or other contract between the prohibiting health care provider and the individual or entity that violates the policy.

(4) Imposition of any other nonmonetary remedy provided for in any lease or contract between the prohibiting health care provider and the individual or entity in violation of the policy.

(d) Nothing in this section shall be construed to prevent, or to allow a prohibiting health care provider to prohibit, any other health care provider, employee, independent contractor, or other person or entity from any of the following:

(1) Participating, or entering into an agreement to participate, in activities under this part, while on premises that are not owned or under the management or direct control of the prohibiting provider or while acting outside the course and scope of the participant's duties as an employee of, or an independent contractor for, the prohibiting health care provider.

(2) Participating, or entering into an agreement to participate, in activities under this part as an attending physician or consulting physician while on premises that are not owned or under the management or direct control of the prohibiting provider.

(e) In taking actions pursuant to subdivision (c), a health care provider shall comply with all procedures required by law, its own policies or procedures, and any contract with the individual or entity in violation of the policy, as applicable.

(f) For purposes of this section:

(1) "Notice" means a separate statement in writing advising of the prohibiting health care provider policy with respect to participating in activities under this part.

(2) "Participating, or entering into an agreement to participate, in activities under this part" means doing or entering into an agreement to do any one or more of the following:

(A) Performing the duties of an attending physician as specified in Section 443.5.

(B) Performing the duties of a consulting physician as specified in Section 443.6.

(C) Performing the duties of a mental health specialist, in the circumstance that a referral to one is made.

(D) Delivering the prescription for, dispensing, or delivering the dispensed aid-in-dying drug pursuant to paragraph (2) of subdivision (b) of, and subdivision (c) of, Section 443.5.

(E) Being present when the qualified individual takes the aid-in-dying drug prescribed pursuant to this part.

(3) "Participating, or entering into an agreement to participate, in activities under this part" does not include doing, or entering into an agreement to do, any of the following:

(A) Diagnosing whether a patient has a terminal disease, informing the patient of the medical prognosis, or determining whether a patient has the capacity to make decisions.

(B) Providing information to a patient about this part.

(C) Providing a patient, upon the patient's request, with a referral to another health care provider for the purposes of participating in the activities authorized by this part.

(g) Any action taken by a prohibiting provider pursuant to this section shall not be reportable under Sections 800 to 809.9, inclusive, of the Business and Professions Code. The fact that a health care provider participates in activities under this part shall not be the sole basis for a complaint or report by another health care provider of unprofessional or dishonorable conduct under Sections 800 to 809.9, inclusive, of the Business and Professions Code.

(h) Nothing in this part shall prevent a health care provider from providing an individual with health care services that do not constitute participation in this part.

443.16. (a) A health care provider may not be sanctioned for any of the following:

(1) Making an initial determination pursuant to the standard of care that an individual has a terminal disease and informing him or her of the medical prognosis.

(2) Providing information about the End of Life Option Act to a patient upon the request of the individual.

(3) Providing an individual, upon request, with a referral to another physician.

(b) A health care provider that prohibits activities under this part in accordance with Section 443.15 shall not sanction an individual health care provider for contracting with a qualified individual to engage in activities authorized by this part if the individual health care provider is acting outside of the course and scope of his or her capacity as an employee or independent contractor of the prohibiting health care provider.

(c) Notwithstanding any contrary provision in this section, the immunities and prohibitions on sanctions of a health care provider are solely reserved for actions of a health care provider taken pursuant to this part. Notwithstanding any contrary provision in this part, health care providers may be sanctioned by their licensing board or agency for conduct and actions constituting unprofessional conduct, including failure to comply in good faith with this part.

443.17. (a) Knowingly altering or forging a request for an aid-in-dying drug to end an individual's life without his or her authorization or concealing or destroying a withdrawal or rescission of a request for an aid-in-dying drug is punishable as a felony if the act is done with the intent or effect of causing the individual's death.

(b) Knowingly coercing or exerting undue influence on an individual to request or ingest an aid-in-dying drug for the purpose of ending his or her life or to destroy a withdrawal or rescission of a request, or to administer an aid-in-dying drug to an individual without his or her knowledge or consent, is punishable as a felony.

(c) For purposes of this section, "knowingly" has the meaning provided in Section 7 of the Penal Code.

(d) The attending physician, consulting physician, or mental health specialist shall not be related to the individual by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the individual's estate upon death.

(e) Nothing in this section shall be construed to limit civil liability.

(f) The penalties in this section do not preclude criminal penalties applicable under any law for conduct inconsistent with the provisions of this section.

443.18. Nothing in this part may be construed to authorize a physician or any other person to end an individual's life by lethal injection, mercy killing, or active euthanasia. Actions taken in accordance with this part shall not, for any purposes, constitute suicide, assisted suicide, homicide, or elder abuse under the law.

443.19. (a) The State Department of Public Health shall collect and review the information submitted pursuant to Section 443.9. The information collected shall be confidential and shall be collected in a manner that protects the privacy of the patient, the patient's family, and any medical provider or pharmacist involved with the patient under the provisions of this part. The information shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.

(b) On or before July 1, 2017, and each year thereafter, based on the information collected in the previous year, the department shall create a report with the information collected from the attending physician followup form and post that report to its Internet Web site. The report shall include, but not be limited to, all of the following based on the information that is provided to the department and on the department's access to vital statistics:

(1) The number of people for whom an aid-in-dying prescription was written.

(2) The number of known individuals who died each year for whom aid-in-dying prescriptions were written, and the cause of death of those individuals.

(3) For the period commencing January 1, 2016, to and including the previous year, cumulatively, the total number of aid-in-dying prescriptions written, the number of people who died due to use of aid-in-dying drugs, and the number of those people who died who were enrolled in hospice or other palliative care programs at the time of death.

(4) The number of known deaths in California from using aid-in-dying drugs per 10,000 deaths in California.

(5) The number of physicians who wrote prescriptions for aid-in-dying drugs.

(6) Of people who died due to using an aid-in-dying drug, demographic percentages organized by the following characteristics:

(A) Age at death.

(B) Education level.

(C) Race.

(D) Sex.

(E) Type of insurance, including whether or not they had insurance.

(F) Underlying illness.

(c) The State Department of Public Health shall make available the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form, as described in Section 443.22, by posting them on its Internet Web site.

443.20. A person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to this part after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or if none is available, shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program.

443.21. Any governmental entity that incurs costs resulting from a qualified individual terminating his or her life pursuant to the provisions of this part in a public place shall have a claim against the estate of the qualified individual to recover those costs and reasonable attorney fees related to enforcing the claim.

443.215. This part shall remain in effect only until January 1, 2026, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2026, deletes or extends that date.

443.22. (a) The Medical Board of California may update the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form, based on those provided in subdivision (b). Upon completion, the State Department of Public Health shall publish the updated forms on its Internet Web site.

(b) Unless and until updated by the Medical Board of California pursuant to this section, the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form shall be in the following form:

ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

A	PATIENT INFORMATION	
	PATIENT'S NAME (LAST, FIRST, M.I.)	DATE OF BIRTH
	PATIENT RESIDENTIAL ADDRESS (STREET, CITY, ZIP CODE)	

B	ATTENDING PHYSICIAN INFORMATION	
	PHYSICIAN'S NAME (LAST, FIRST, M.I.)	TELEPHONE NUMBER ( ) —
	MAILING ADDRESS (STREET, CITY, ZIP CODE)	
	PHYSICIAN'S LICENSE NUMBER	

C	CONSULTING PHYSICIAN INFORMATION	
	PHYSICIAN'S NAME (LAST, FIRST, M.I.)	TELEPHONE NUMBER ( ) —
	MAILING ADDRESS (STREET, CITY, ZIP CODE)	
	PHYSICIAN'S LICENSE NUMBER	

D	ELIGIBILITY DETERMINATION
	1. TERMINAL DISEASE
	2. CHECK BOXES FOR COMPLIANCE: ☐ 1. Determination that the patient has a terminal disease. ☐ 2. Determination that patient is a resident of California. ☐ 3. Determination that patient has the capacity to make medical decisions** ☐ 4. Determination that patient is acting voluntarily. ☐ 5. Determination of capacity by mental health specialist, if necessary. ☐ 6. Determination that patient has made his/her decision after being fully informed of: ☐ a) His or her medical diagnosis; and ☐ b) His or her prognosis; and ☐ c) The potential risks associated with ingesting the requested aid-in-dying drug; ☐ d) The probable result of ingesting the aid-in-dying drug; ☐ e) The possibility that he or she may choose to obtain the aid-in-dying drug but not take it

ATTENDING PHYSICIAN CHECKLIST &
COMPLIANCE FORM

E	ADDITIONAL COMPLIANCE REQUIREMENTS

☐ 1. Counseled patient about the importance of all of the following:
☐ a) Maintaining the aid-in-dying drug in a safe and secure location until the time the qualified individual will ingest it;
☐ b) Having another person present when he or she ingests the aid-in-dying drug;
☐ c) Not ingesting the aid-in-dying drug in a public place;
☐ d) Notifying the next of kin of his or her request for an aid-in-dying drug. (an individual who declines or is unable to notify next of kin shall not have his or her request denied for that reason); and
☐ e) Participating in a hospice program or palliative care program.
☐ 2. Informed patient of right to rescind request (1st time)
☐ 3. Discussed the feasible alternatives, including, but not limited to, comfort care, hospice care, palliative care and pain control.
☐ 4. Met with patient one-on-one, except in the presence of an interpreter, to confirm the request is not coming from coercion
☐ 5. First oral request for aid-in-dying: _____/_____/_____ Attending physician initials:_____
☐ 6. Second oral request for aid-in-dying:_____/_____/_____ Attending physician initials:_____
☐ 7. Written request submitted: _____/_____/_____ Attending physician initials:_____
☐ 8. Offered patient right to rescind (2nd time)

F	PATIENT'S MENTAL STATUS

Check one of the following **(required)**:

☐ I have determined that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

☐ I have referred the patient to the mental health specialist**** listed below for one or more consultations to determine that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

☐ If a referral was made to a mental health specialist, the mental health specialist has determined that the patient is not suffering from impaired judgment due to a mental disorder

Mental health specialist's information, if applicable:

MENTAL HEALTH SPECIALIST NAME

MENTAL HEALTH SPECIALIST TITLE & LICENSE NUMBER

MENTAL HEALTH SPECIALIST ADDRESS (STREET, CITY, ZIP CODE)

ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

G	MEDICATION PRESCRIBED	
	PHARMACIST NAME	TELEPHONE NUMBER ( ) —

1. Aid-in-dying medication prescribed:
   - ☐ a. Name:_____
   - ☐ b. Dosage:_____
2. Antiemetic medication prescribed:
   - ☐ a. Name:_____
   - ☐ b. Dosage:_____
3. Method prescription was delivered:
   - ☐ a. In person
   - ☐ b. By mail
   - ☐ c. Electronically
4. Date medication was prescribed:_____/_____/_____

		PHYSICIAN'S SIGNATURE	DATE
	X	NAME (PLEASE PRINT)	

** "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make

****"Mental Health Specialist" means a psychiatrist or a licensed psychologist.

CONSULTING PHYSICIAN COMPLIANCE FORM

A	PATIENT INFORMATION	
	PATIENT'S NAME (LAST, FIRST, M.I.)	DATE OF BIRTH

B	ATTENDING PHYSICIAN	
	ATTENDING PHYSICIAN'S NAME (LAST, FIRST, M.I.)	TELEPHONE NUMBER ( ) . —

C CONSULTING PHYSICIAN'S REPORT

1. TERMINAL DISEASE	DATE OF EXAMINATION(S)

2. Check boxes for compliance. *(Both the attending and consulting physicians must make these determinations.)*

- ☐ 1. Determination that the patient has a terminal disease.
- ☐ 2. Determination that patient has the mental capacity to make medical decisions.**
- ☐ 3. Determination that patient is acting voluntarily.
- ☐ 4. Determination that patient has made his/her decision after being fully informed of:
- ☐ a) His or her medical diagnosis; and
- ☐ b) His or her prognosis; and
- ☐ c) The potential risks associated with taking the drug to be prescribed; and
- ☐ d) The potential result of taking the drug to be prescribed; and
- ☐ e) The feasible alternatives, including, but not limited to, comfort care, hospice care, palliative care and pain control.

D PATIENT'S MENTAL STATUS

Check one of the following **(required)**:

- ☐ I have determined that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ I have referred the patient to the mental health specialist**** listed below for one or more consultations to determine that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ If a referral was made to a mental health specialist, the mental health specialist has determined that the patient is not suffering from impaired judgment due to a mental disorder

MENTAL HEALTH SPECIALIST'S NAME	TELEPHONE NUMBER ( ) —	DATE

E CONSULTANT'S INFORMATION

X	PHYSICIAN'S SIGNATURE	DATE
	NAME (PLEASE PRINT)	
MAILING ADDRESS		
CITY, STATE AND ZIP CODE		TELEPHONE NUMBER ( ) —

** "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make

****"Mental Health Specialist" means a psychiatrist or a licensed psychologist.

ATTENDING PHYSICIAN FOLLOW-UP FORM

The End of Life Option Act requires physicians who write a prescription for an aid-in-dying drug to complete this follow-up form within **30 calendar days** of a patient's death, whether from ingestion of the aid-in-dying drug obtained under the Act or from any other cause.

For the State Department of Public Health to accept this form, it must be signed by the attending physician, whether or not he or she was present at the patient's time of death.

This form should be mailed or sent electronically to the State Department of Public Health. All information is kept strictly confidential.

Date: _____/_____/_____

Patient name: _____

Attending physician name: _____

Did the patient die from ingesting the aid-in-dying drug, from their underlying illness, or from another cause such as terminal sedation or ceasing to eat or drink?

- ☐ **Aid-in-dying drug** (lethal dose) → Please sign below and go to page 2.
  Attending physician signature:_____
- ☐ **Underlying illness** → There is no need to complete the rest of the form. Please sign below.
  Attending physician signature:_____
- ☐ **Other** → There is no need to complete the rest of the form. Please specify the circumstances surrounding the patient's death and sign
  Please specify:
  _____
  _____

Attending physician signature:_____

PART A and PART B should only be completed if the patient died from ingesting the lethal dose of the aid-in-dying drug.

Please read carefully the following to determine which situation applies. Check the box that indicates the scenario and complete the remainder of the form accordingly.

- ☐ The attending physician was present at the time of death.
  → The attending physician must complete this form in its entirety and sign Part A and Part B.
- ☐ The attending physician was not present at the time of death, but another licensed health care provider was present.
  → The licensed health care provider must complete and sign Part A of this form. The attending physician must complete and sign Part B of the form.
- ☐ Neither the attending physician nor another licensed health care provider was present at the time of death.
  → Part A may be left blank. The attending physician must complete and sign Part B of the form.

ATTENDING PHYSICIAN FOLLOW-UP FORM

PART A: To be completed and signed by the attending physician or another licensed health care provider present at death:

1. Was the attending physician at the patient's bedside when the patient took the aid-in-dying drug?
   - ☐ Yes
   - ☐ No

If no: Was another physician or trained health care provider present when the patient ingested the aid-in-dying drug?
   - ☐ Yes, another physician
   - ☐ Yes, a trained health-care provider/volunteer
   - ☐ No
   - ☐ Unknown

2. Was the attending physician at the patient's bedside at the time of death?
   - ☐ Yes
   - ☐ No

If no: Was another physician or a licensed health care provider present at the patient's time of death?
   - ☐ Yes, another physician or licensed health care provider
   - ☐ No
   - ☐ Unknown

3. On what day did the patient consume the lethal dose of the aid-in-dying?
_____/_____/_____ (month/day/year) ☐ Unknown

4. On what day did the patient die after consuming the lethal dose of the aid-in-dying drug?
_____/____/_____ (month/day/year) ☐ Unknown

5. Where did the patient ingest the lethal dose of the aid-in-dying drug?
   - ☐ Private home
   - ☐ Assisted-living residence
   - ☐ Nursing home
   - ☐ Acute care hospital in-patient
   - ☐ In-patient hospice resident
   - ☐ Other (specify)_____
   - ☐ Unknown

6. What was the time between the ingestion of the lethal dose of aid-in-dying drug and unconsciousness?
Minutes_____ and/or Hours_____ ☐Unknown

7. What was the time between lethal medication ingestion and death?
Minutes_____ and/or Hours_____ ☐Unknown

ATTENDING PHYSICIAN FOLLOW-UP FORM

8. Were there any complications that occurred after the patient took the lethal dose of the aid-in-dying drug?

- ☐ Yes- vomiting, emesis
- ☐ Yes-regained consciousness
- ☐ No Complications
- ☐ Other- Please describe:_____
- ☐ Unknown

9. Was the Emergency Medical System activated for any reason after ingesting the lethal dose of the aid-in-dying drug?

- ☐ Yes- Please describe:_____
- ☐ No
- ☐ Unknown

10. At the time of ingesting the lethal dose of the aid-in-dying drug, was the patient receiving hospice care?

- ☐ Yes
- ☐ No, refused care
- ☐ No, other (specify) _____

Signature of attending physician present at time of death: _____

Name of Licensed Health Care Provider present at time of death if not attending physician:_____

Signature of Licensed Health Care Provider: _____

ATTENDING PHYSICIAN FOLLOW-UP FORM

PART B: To be completed and signed by the attending physician

12. On what date was the prescription written for the aid-in-dying drug? ____/____/____

13. When the patient initially requested a prescription for the aid-in-dying drug, was the patient receiving hospice care?

- ☐ Yes
- ☐ No, refused care
- ☐ No, other (specify) _____

14. What type of health-care coverage did the patient have for their underlying illness? (*Check all that apply.*)

- ☐ Medicare
- ☐ Medi-cal
- ☐ Covered California
- ☐ V.A.
- ☐ Private Insurance
- ☐ No insurance
- ☐ Had insurance, don't know type

15. Possible concerns that may have contributed to the patient's decision to request a prescription for aid-in-dying drug Please check "yes," "no," or "Don't' know," depending on whether or not you believe that concern contributed to their request (Please check as many boxes as you think may apply)

A concern about . . .

- **His or her terminal condition representing a steady loss of autonomy**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **The decreasing ability to participate in activities that made life enjoyable**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **The loss of control of bodily functions**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **Persistent and uncontrollable pain and suffering**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **A loss of Dignity**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **Other concerns** (specify): _____

Signature of attending physician: _____

SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 443.19 to the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

(a) Any limitation to public access to personally identifiable patient data collected pursuant to Section 443.19 of the Health and Safety Code as proposed to be added by this act is necessary to protect the privacy rights of the patient and his or her family.

(b) The interests in protecting the privacy rights of the patient and his or her family in this situation strongly outweigh the public interest in having access to personally identifiable data relating to services.

(c) The statistical report to be made available to the public pursuant to subdivision (b) of Section 443.19 of the Health and Safety Code is sufficient to satisfy the public's right to access.

SEC. 3. The provisions of this part are severable. If any provision of this part 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.

SEC. 4. 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

Attachment 4

AMENDED IN SENATE JULY 1, 2015

AMENDED IN ASSEMBLY MAY 28, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1306

Introduced by Assembly Member Burke
(Coauthor: Assembly Member Mark Stone)

February 27, 2015

An act to amend Sections 650.01, *650.02*, 2725.1, 2746.2, 2746.5, 2746.51, 2746.52, 4061, 4076, and 4170 of, and to add Section 2746.6 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1306, as amended, Burke. Healing arts: certified nurse-midwives: scope of practice.

(1) Existing law, the Nursing Practice Act, provides for the licensure and regulation of the practice of nursing by the Board of Registered Nursing and authorizes the board to issue a certificate to practice nurse-midwifery to a person who meets educational standards established by the board or the equivalent of those educational standards. The act makes the violation of any of its provisions a misdemeanor punishable upon conviction by imprisonment in the county jail for not less than 10 days nor more than one year, or by a fine of not less than $20 nor more than $1,000, or by both that fine and imprisonment.

This bill would additionally require an applicant for a certificate to practice nurse-midwifery to provide evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board. This bill would also require the board to create and appoint a Nurse-Midwifery Advisory Council

consisting of certified nurse-midwives in good standing with experience in hospital ~~and nonhospital practice~~ settings, *alternative birth settings, and home settings*, a nurse-midwife educator, as specified, and a consumer of midwifery care. This bill would require *the council to consist of a majority of certified nurse-midwives and would require* the council to make recommendations to the board on all matters related to nurse-midwifery practice, education, *disciplinary actions, standards of care,* and other matters specified by the board, and would require the council to meet regularly, but at least twice a year. This bill would ~~also~~ prohibit corporations and other artificial legal entities from having professional rights, privileges, or powers under the act, except as specified. *The bill would authorize specified entities to employ a certified nurse-midwife and charge for professional services rendered by that certified nurse-midwife, as provided.*

(2) The act authorizes a certified nurse-midwife, under the supervision of a licensed physician and surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother, and immediate care for the newborn, and provides that the practice of nurse-midwifery constitutes the furthering or undertaking by a certified person, under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal.

This bill would delete those provisions and would instead authorize a certified nurse-midwife to manage a full range of ~~primary health~~ *gynecological and obstetric* care services for women from adolescence beyond menopause, ~~including, but not limited to, gynecologic and family planning services.~~ *as provided.* The bill would authorize a certified nurse-midwife to practice in ~~all~~ *specified* settings, including, but not limited to, a home *setting*. This bill would declare that the practice of nurse-midwifery within a health care system provides for consultation, collaboration, or referral as indicated by the health status of the client and the resources of the medical personnel available in the setting of care, and would provide that the practice of nurse-midwifery emphasizes informed consent, preventive care, and early detection and referral of complications to a physician and surgeon. ~~This bill would authorize a certified nurse-midwife to provide peripartum care in an out-of-hospital setting to low-risk women with uncomplicated singleton-term pregnancies who are expected to have uncomplicated birth.~~

(3) The act authorizes a certified nurse-midwife to furnish and order drugs or devices incidentally to the provision of family planning services, routine health care or perinatal care, and care rendered consistently with the certified nurse-midwife's educational preparation in specified facilities and clinics, and only in accordance with standardized procedures and protocols, as specified.

This bill would delete the requirement that drugs or devices are furnished or ordered in accordance with standardized procedures and protocols. The bill would authorize a certified nurse-midwife to furnish and order drugs or devices in connection with care rendered in a home, and would authorize a certified nurse-midwife to directly procure supplies and devices, to order, obtain, and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a certified nurse-midwife and that are consistent with nurse-midwifery education preparation.

(4) The act also authorizes a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a licensed acute care hospital and a licensed alternate birth center, if certain requirements are met, including, but not limited to, that episiotomies are performed pursuant to protocols developed and approved by the supervising physician and surgeon.

This bill would also authorize a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a home, and would delete all requirements that those procedures be performed pursuant to protocols developed and approved by the supervising physician and surgeon. The bill would require a certified nurse-midwife to provide emergency care to a patient during times when a physician and surgeon is unavailable.

This bill would provide that a consultative relationship between a certified nurse-midwife and a physician and surgeon by it self is not a basis for finding the physician and surgeon liable for any acts or omissions on the part of the certified nurse-midwife. The bill would also update cross-references as needed.

(5) Because the act makes a violation of any of its provisions a misdemeanor, this bill would expand the scope of an existing crime and therefore this bill would impose a state-mandated local program.

(6) Existing law prohibits a licensee, as defined, from referring a person for laboratory, diagnostic, nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home

infusion therapy, or diagnostic imaging goods or services if the licensee or his or her immediate family has a financial interest with the person or entity that receives the referral, and makes a violation of that prohibition punishable as a misdemeanor. Under existing ~~law~~ *law,* the Medical Board of California is required to review the facts and circumstances of any conviction for violating the prohibition, and to take appropriate disciplinary action if the licensee has committed unprofessional conduct. *Existing law provides that, among other exceptions, this prohibition does not apply to a licensee who refers a person to a health facility if specified conditions are met.*

This bill would include a certified nurse-midwife under the definition of a licensee, which would expand the scope of an existing crime and therefore impose a state-mandated local program. The bill would ~~also~~ require the Board of Registered Nursing to review the facts and circumstances of any conviction of a certified nurse-midwife for violating that prohibition, and would require the board to take appropriate disciplinary action if the certified nurse-midwife has committed unprofessional conduct. *The bill would additionally authorize a licensee to refer a person to a licensed alternative birth center, as defined, or a nationally accredited alternative birth center.*

(7) 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. Section 650.01 of the Business and Professions Code is amended to read:

650.01. (a) Notwithstanding Section 650, or any other law, it is unlawful for a licensee to refer a person for laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the licensee or his or her immediate family has a financial interest with the person or in the entity that receives the referral.

(b) For purposes of this section and Section 650.02, the following shall apply:

(1) "Diagnostic imaging" includes, but is not limited to, all X-ray, computed axial tomography, magnetic resonance imaging nuclear medicine, positron emission tomography, mammography, and ultrasound goods and services.

(2) A "financial interest" includes, but is not limited to, any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the licensee refers a person for a good or service specified in subdivision (a). A financial interest also exists if there is an indirect financial relationship between a licensee and the referral recipient including, but not limited to, an arrangement whereby a licensee has an ownership interest in an entity that leases property to the referral recipient. Any financial interest transferred by a licensee to any person or entity or otherwise established in any person or entity for the purpose of avoiding the prohibition of this section shall be deemed a financial interest of the licensee. For purposes of this paragraph, "direct or indirect payment" shall not include a royalty or consulting fee received by a physician and surgeon who has completed a recognized residency training program in orthopedics from a manufacturer or distributor as a result of his or her research and development of medical devices and techniques for that manufacturer or distributor. For purposes of this paragraph, "consulting fees" means those fees paid by the manufacturer or distributor to a physician and surgeon who has completed a recognized residency training program in orthopedics only for his or her ongoing services in making refinements to his or her medical devices or techniques marketed or distributed by the manufacturer or distributor, if the manufacturer or distributor does not own or control the facility to which the physician is referring the patient. A "financial interest" shall not include the receipt of capitation payments or other fixed amounts that are prepaid in exchange for a promise of a licensee to provide specified health care services to specified beneficiaries. A "financial interest" shall not include the receipt of remuneration by a medical director of a hospice, as defined in Section 1746 of the Health and Safety Code, for specified services if the arrangement is set out in writing,

and specifies all services to be provided by the medical director, the term of the arrangement is for at least one year, and the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between parties.

(3) For the purposes of this section, "immediate family" includes the spouse and children of the licensee, the parents of the licensee, and the spouses of the children of the licensee.

(4) "Licensee" means a physician as defined in Section 3209.3 of the Labor Code, and a certified nurse-midwife as defined in Article 2.5 (commencing with Section 2746) of Chapter 6 of Division 2 of the Business and Professions Code.

(5) "Licensee's office" means either of the following:

(A) An office of a licensee in solo practice.

(B) An office in which services or goods are personally provided by the licensee or by employees in that office, or personally by independent contractors in that office, in accordance with other provisions of law. Employees and independent contractors shall be licensed or certified when licensure or certification is required by law.

(6) "Office of a group practice" means an office or offices in which two or more licensees are legally organized as a partnership, professional corporation, or not-for-profit corporation, licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code, for which all of the following apply:

(A) Each licensee who is a member of the group provides substantially the full range of services that the licensee routinely provides, including medical care, consultation, diagnosis, or treatment through the joint use of shared office space, facilities, equipment, and personnel.

(B) Substantially all of the services of the licensees who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group, except in the case of a multispecialty clinic, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code, physician services are billed in the name of the multispecialty clinic and amounts so received are treated as receipts of the multispecialty clinic.

(C) The overhead expenses of, and the income from, the practice are distributed in accordance with methods previously determined by members of the group.

(c) It is unlawful for a licensee to enter into an arrangement or scheme, such as a cross-referral arrangement, that the licensee knows, or should know, has a principal purpose of ensuring referrals by the licensee to a particular entity that, if the licensee directly made referrals to that entity, would be in violation of this section.

(d) No claim for payment shall be presented by an entity to any individual, third party payer, or other entity for a good or service furnished pursuant to a referral prohibited under this section.

(e) No insurer, self-insurer, or other payer shall pay a charge or lien for any good or service resulting from a referral in violation of this section.

(f) A licensee who refers a person to, or seeks consultation from, an organization in which the licensee has a financial interest, other than as prohibited by subdivision (a), shall disclose the financial interest to the patient, or the parent or legal guardian of the patient, in writing, at the time of the referral or request for consultation.

(1) If a referral, billing, or other solicitation is between one or more licensees who contract with a multispecialty clinic pursuant to subdivision (*l*) of Section 1206 of the Health and Safety Code or who conduct their practice as members of the same professional corporation or partnership, and the services are rendered on the same physical premises, or under the same professional corporation or partnership name, the requirements of this subdivision may be met by posting a conspicuous disclosure statement at the registration area or by providing a patient with a written disclosure statement.

(2) If a licensee is under contract with the Department of Corrections or the California Youth Authority, and the patient is an inmate or parolee of either respective department, the requirements of this subdivision shall be satisfied by disclosing financial interests to either the Department of Corrections or the California Youth Authority.

(g) A violation of subdivision (a) shall be a misdemeanor. In the case of a licensee who is a physician, the Medical Board of California shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate

disciplinary action if the licensee has committed unprofessional conduct. In the case of a licensee who is a certified nurse-midwife, the Board of Registered Nursing shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate disciplinary action if the licensee has committed unprofessional conduct. Violations of this section may also be subject to civil penalties of up to five thousand dollars ($5,000) for each offense, which may be enforced by the Insurance Commissioner, Attorney General, or a district attorney. A violation of subdivision (c), (d), or (e) is a public offense and is punishable upon conviction by a fine not exceeding fifteen thousand dollars ($15,000) for each violation and appropriate disciplinary action, including revocation of professional licensure, by the Medical Board of California, the Board of Registered Nursing, or other appropriate governmental agency.

(h) This section shall not apply to referrals for services that are described in and covered by Sections 139.3 and 139.31 of the Labor Code.

(i) This section shall become operative on January 1, 1995.

SEC. 2. Section 650.02 of the Business and Professions Code is amended to read:

650.02. The prohibition of Section 650.01 shall not apply to or restrict any of the following:

(a) A licensee may refer a patient for a good or service otherwise prohibited by subdivision (a) of Section 650.01 if the licensee's regular practice is located where there is no alternative provider of the service within either 25 miles or 40 minutes traveling time, via the shortest route on a paved road. If an alternative provider commences furnishing the good or service for which a patient was referred pursuant to this subdivision, the licensee shall cease referrals under this subdivision within six months of the time at which the licensee knew or should have known that the alternative provider is furnishing the good or service. A licensee who refers to or seeks consultation from an organization in which the licensee has a financial interest under this subdivision shall disclose this interest to the patient or the patient's parents or legal guardian in writing at the time of referral.

(b) A licensee, when the licensee or his or her immediate family has one or more of the following arrangements with another

licensee, a person, or an entity, is not prohibited from referring a patient to the licensee, person, or entity because of the arrangement:

(1) A loan between a licensee and the recipient of the referral, if the loan has commercially reasonable terms, bears interest at the prime rate or a higher rate that does not constitute usury, is adequately secured, and the loan terms are not affected by either party's referral of any person or the volume of services provided by either party.

(2) A lease of space or equipment between a licensee and the recipient of the referral, if the lease is written, has commercially reasonable terms, has a fixed periodic rent payment, has a term of one year or more, and the lease payments are not affected by either party's referral of any person or the volume of services provided by either party.

(3) Ownership of corporate investment securities, including shares, bonds, or other debt instruments that may be purchased on terms generally available to the public and that are traded on a licensed securities exchange or NASDAQ, do not base profit distributions or other transfers of value on the licensee's referral of persons to the corporation, do not have a separate class or accounting for any persons or for any licensees who may refer persons to the corporation, and are in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous three fiscal years, stockholder equity exceeding seventy-five million dollars ($75,000,000).

(4) Ownership of shares in a regulated investment company as defined in Section 851(a) of the federal Internal Revenue Code, if the company had, at the end of the company's most recent fiscal year, or on average during the previous three fiscal years, total assets exceeding seventy-five million dollars ($75,000,000).

(5) A one-time sale or transfer of a practice or property or other financial interest between a licensee and the recipient of the referral if the sale or transfer is for commercially reasonable terms and the consideration is not affected by either party's referral of any person or the volume of services provided by either party.

(6) A personal services arrangement between a licensee or an immediate family member of the licensee and the recipient of the referral if the arrangement meets all of the following requirements:

(A) It is set out in writing and is signed by the parties.

(B) It specifies all of the services to be provided by the licensee or an immediate family member of the licensee.

(C) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(D) A person who is referred by a licensee or an immediate family member of the licensee is informed in writing of the personal services arrangement that includes information on where a person may go to file a complaint against the licensee or the immediate family member of the licensee.

(E) The term of the arrangement is for at least one year.

(F) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(G) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.

(c) (1) A licensee may refer a person to a health facility, as defined in Section 1250 of the Health and Safety Code, *a licensed alternative birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code,* or to any facility*, or nationally accredited alternative birth center,* owned or leased by a health facility, if the recipient of the referral does not compensate the licensee for the patient referral, and any equipment lease arrangement between the licensee and the referral recipient complies with the requirements of paragraph (2) of subdivision (b).

(2) Nothing shall preclude this subdivision from applying to a licensee solely because the licensee has an ownership or leasehold interest in an entire health facility or an entity that owns or leases an entire health facility.

(3) A licensee may refer a person to a health facility for any service classified as an emergency under subdivision (a) or (b) of Section 1317.1 of the Health and Safety Code.

(4) A licensee may refer a person to any organization that owns or leases a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code if the licensee is not compensated for the patient referral, the licensee does not

receive any payment from the recipient of the referral that is based or determined on the number or value of any patient referrals, and any equipment lease arrangement between the licensee and the referral recipient complies with the requirements of paragraph (2) of subdivision (b). For purposes of this paragraph, the ownership may be through stock or membership, and may be represented by a parent holding company that solely owns or controls both the health facility organization and the affiliated organization.

(d) A licensee may refer a person to a nonprofit corporation that provides physician services pursuant to subdivision (*l*) of Section 1206 of the Health and Safety Code if the nonprofit corporation is controlled through membership by one or more health facilities or health facility systems and the amount of compensation or other transfer of funds from the health facility or nonprofit corporation to the licensee is fixed annually, except for adjustments caused by physicians joining or leaving the groups during the year, and is not based on the number of persons utilizing goods or services specified in Section 650.01.

(e) A licensee compensated or employed by a university may refer a person for a physician service, to any facility owned or operated by the university, or to another licensee employed by the university, provided that the facility or university does not compensate the referring licensee for the patient referral. In the case of a facility that is totally or partially owned by an entity other than the university, but that is staffed by university physicians, those physicians may not refer patients to the facility if the facility compensates the referring physicians for those referrals.

(f) The prohibition of Section 650.01 shall not apply to any service for a specific patient that is performed within, or goods that are supplied by, a licensee's office, or the office of a group practice. Further, the provisions of Section 650.01 shall not alter, limit, or expand a licensee's ability to deliver, or to direct or supervise the delivery of, in-office goods or services according to the laws, rules, and regulations governing his or her scope of practice.

(g) The prohibition of Section 650.01 shall not apply to cardiac rehabilitation services provided by a licensee or by a suitably trained individual under the direct or general supervision of a licensee, if the services are provided to patients meeting the criteria for Medicare reimbursement for the services.

(h) The prohibition of Section 650.01 shall not apply if a licensee is in the office of a group practice and refers a person for services or goods specified in Section 650.01 to a multispecialty clinic, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code.

(i) The prohibition of Section 650.01 shall not apply to health care services provided to an enrollee of 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).

(j) The prohibition of Section 650.01 shall not apply to a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, or a request by a radiation oncologist for radiation therapy if those services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician.

(k) This section shall not apply to referrals for services that are described in and covered by Sections 139.3 and 139.31 of the Labor Code.

(*l*) This section shall become operative on January 1, 1995.

~~SEC. 2.~~

SEC. 3. Section 2725.1 of the Business and Professions Code is amended to read:

2725.1. (a) Notwithstanding any other law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon or an order by a certified nurse-midwife, nurse practitioner, or physician assistant issued pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, if the registered nurse is functioning within a licensed primary care clinic as defined in subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b), (c), (h), or (j) of Section 1206 of, the Health and Safety Code.

(b) No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to Section

2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

(c) This section shall not be construed to limit any other authority granted to a certified nurse-midwife pursuant to Article 2.5 (commencing with Section 2746), to a nurse practitioner pursuant to Article 8 (commencing with Section 2834), or to a physician assistant pursuant to Chapter 7.7 (commencing with Section 3500).

(d) This section shall not be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed pursuant to Chapter 9 (commencing with Section 4000).

~~SEC. 3.~~

SEC. 4. Section 2746.2 of the Business and Professions Code is amended to read:

2746.2. (a) Each applicant shall show by evidence satisfactory to the board that he or she has met the educational standards established by the board or has at least the equivalent thereof, including evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board.

(b) The board shall create and appoint a Nurse-Midwifery Advisory Council consisting of certified nurse-midwives in good standing with experience in hospital ~~and nonhospital practice settings,~~ *settings, alternative birth center settings, and home settings,* a nurse-midwife educator who has demonstrated familiarity with ~~consumer needs, collegial practice and accompanied liability, and related~~ educational standards in the delivery of maternal-child health care, ~~and~~ a consumer of midwifery ~~care.~~ *care, and at least two qualified physicians appointed by the Medical Board of California, including an obstetrician that has experience working with nurse-midwives.* The council *membership shall consist of a majority of certified nurse-midwives and* shall make recommendations to the board on all matters related to nurse-midwifery practice, education, and

other matters as specified by the board. The council shall meet regularly, but at least twice a year.

(c) Corporations and other artificial legal entities shall have no professional rights, privileges, or powers. However, the Board of Registered Nursing may in its discretion, after such investigation and review of such documentary evidence as it may require, and under regulations adopted by it, grant approval of the employment of licensees on a salary basis by licensed charitable institutions, foundations, or clinics, if no charge for professional services rendered patients is made by any such institution, foundation, or clinic.

(d) Notwithstanding subdivision (c), the following entities may employ a certified nurse-midwife and charge for professional services rendered by a certified nurse-midwife; however, the entity shall not interfere with, control, or otherwise direct the professional judgment of a certified nurse-midwife:

(1) A clinic operated under subdivision (p) of Section 1206 of the Health and Safety Code.

(2) A hospital owned and operated by a health care district pursuant to Division 23 (commencing with Section 32000) of the Health and Safety Code.

(3) A clinic operated primarily for the purpose of medical education or nursing education by a public or private nonprofit university medical school, which is approved by the Medical Board or the Osteopathic Medical Board of California, provided the certified nurse-midwife holds an academic appointment on the faculty of the university, including, but not limited to, the University of California medical schools and hospitals.

(4) A licensed alternative birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, or a nationally accredited alternative birth center owned or operated by a nursing corporation, as defined in Section 2775 of the Business and Professions Code.

~~SEC. 4.~~

SEC. 5. Section 2746.5 of the Business and Professions Code is amended to read:

2746.5. (a) The certificate to practice nurse-midwifery authorizes the holder to manage a full range of primary ~~health~~ *gynecological and obstetric* care services for women from adolescence to beyond ~~menopause.~~ *menopause, consistent with*

the Core Competencies for Basic Midwifery practice promulgated by the American College of Nurse-Midwives, or its successor national professional organization, as approved by the board. These services include, but are not limited to, primary health care, gynecologic and family planning services, preconception care, care during pregnancy, childbirth, and the postpartum period, immediate care of the newborn, and treatment of male partners for sexually transmitted ~~infections. A certified nurse-midwife is authorized to practice in all settings, including, but not limited to, private practice, clinics, hospitals, birth centers, and homes.~~ *infections, utilizing consultation, collaboration, or referral to appropriate levels of health care services, as indicated.*

(b) A certified nurse-midwife may practice in the following settings:

~~(b)~~

(1) A licensed clinic as described in Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code.

(2) A facility as described in Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(3) A facility as described in Chapter 2.5 (commencing with Section 1440) of Division 2 of the Health and Safety Code.

(4) A medical group practice, including a professional medical corporation, a medical partnership, a medical foundation exempt from licensure pursuant to Section 1206 of the Health and Safety Code, or another lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services.

(5) A licensed alternative birth center, as described in Section 1204 of the Health and Safety Code, or nationally accredited birth center.

(6) A nursing corporation, as defined in Section 2775 of the Business and Professions Code.

(7) A home setting.

(A) Except as provided in subparagraph (B) of this paragraph, a certified nurse-midwife shall assist during pregnancy and childbirth in the home setting only when all of the following conditions apply:

(i) There is the absence of all of the following:

(I) Any preexisting maternal disease or condition likely to complicate the pregnancy.

(II) Disease arising from the pregnancy likely to cause significant maternal and/or fetal compromise.

(III) Prior caesarean delivery.

(ii) There is a singleton fetus.

(iii) There is cephalic presentation at the onset of labor.

(iv) The gestational age of the fetus is greater than 370/7 weeks and less than 420/7 completed weeks of pregnancy at the onset of labor.

(v) Labor is spontaneous or induced in an outpatient setting.

(B) If a potential certified nurse-midwife client meets the conditions specified in clauses (ii) to (v), inclusive, of subparagraph (A), but fails to meet the conditions specified in clause (i) of subparagraph (A), and the woman still desires to be a client of the certified nurse-midwife, the certified nurse-midwife shall consult with a physician and surgeon trained in obstetrics and gynecology. A certified nurse-midwife may assist the woman in pregnancy and childbirth only if a physician and surgeon trained in obstetrics and gynecology is consulted and the physician and surgeon who performed the consultation determines that the risk factors presented by her disease or condition are not likely to significantly affect the course of pregnancy and childbirth.

(c) As used in this chapter, the practice of nurse-midwifery within a health care system provides for consultation, collaboration, or referral as indicated by the health status of the patient and the resources and medical personnel available in the setting of care. ~~When providing peripartum care in out-of-hospital settings, the certified nurse-midwife shall only provide care to low-risk women with uncomplicated singleton-term pregnancies who are expected to have an uncomplicated birth.~~ The practice of nurse-midwifery care emphasizes informed consent, preventive care, and early detection and referral of complications to physicians and surgeons. While practicing in a hospital setting, the certified nurse-midwife shall collaboratively care for women with more complex health needs.

(d) A certified nurse-midwife practicing under subdivision (a) shall be subject to all credentialing and quality standards held by the facility in which he or she practices. The peer review body shall include nurse-midwives as part of the peer review body that reviews nurse-midwives. The peer review body of that facility shall impose standards that assure quality and patient safety in their

facility. The standards shall be approved by the relevant governing body unless found by a court to be arbitrary and capricious.

~~(c)~~

(e) The practice of nurse-midwifery does not include the assisting of childbirth by any forcible, or mechanical means, nor the performance of any version of those means.

(f) A certified nurse-midwife is not authorized to practice medicine and surgery by the provisions of this chapter.

~~(d)~~

(g) Any regulations promulgated by a state department that affect the scope of practice of a certified nurse-midwife shall be developed in consultation with the board *and the Nurse-Midwifery Advisory Council*.

~~SEC. 5.~~

SEC. 6. Section 2746.51 of the Business and Professions Code is amended to read:

2746.51. (a) Neither this chapter nor any other law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when the drugs or devices are furnished or ordered related to the provision of any of the following:

(1) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(2) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(3) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(4) Care rendered in a home pursuant to subdivision (a) of Section 2746.5.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph.

(3) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) when the drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (1) to (3), inclusive, of subdivision (b). *In a nonhospital setting, a Schedule II controlled substance shall be furnished by a certified nurse-midwife only during labor and delivery and only after a consultation with a physician and surgeon.*

(d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of a physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(f) A certified nurse-midwife is authorized to directly procure supplies and devices, to order, obtain, and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a certified nurse-midwife and consistent with nurse-midwifery education preparation.

~~SEC. 6.~~

SEC. 7. Section 2746.52 of the Business and Professions Code is amended to read:

2746.52. (a) Notwithstanding Section 2746.5, the certificate to practice nurse-midwifery authorizes the holder to perform and repair episiotomies, and to repair first-degree and second-degree lacerations of the perineum, in a licensed acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, in a licensed alternate birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, *or a nationally accredited birth center,* and in a home pursuant to ~~subdivision (a)~~ *paragraph (7) of subdivision (b)* of Section 2746.5.

(b) The certified nurse-midwife performing and repairing first-degree and second-degree lacerations of the perineum shall do both of the following:

(1) Ensure that all complications are referred to a physician and surgeon immediately.

(2) Ensure immediate care of patients who are in need of care beyond the scope of practice of the certified nurse-midwife, or

provide emergency care for times when a physician and surgeon is not available.

~~SEC. 7.~~

SEC. 8. Section 2746.6 is added to the Business and Professions Code, to read:

2746.6. A consultative relationship between a certified nurse-midwife and a physician and surgeon shall not, by ~~it self,~~ *itself,* provide the basis for finding a physician and surgeon liable for any act or omission of the certified nurse-midwife.

~~SEC. 8.~~

SEC. 9. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) A manufacturer's sales representative shall not distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. However, a certified nurse-midwife who functions pursuant to Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to a protocol described in Section 3502.1, or a naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725, 3502.1, or 3640.5, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, physician assistant, or naturopathic doctor, shall be defined within the standardized procedure, protocol, or practice agreement.

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

shall be preserved by the supplier with the records required by Section 4059.

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

~~SEC. 9.~~

SEC. 10. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

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

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

(3) The name of the patient or patients.

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

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who

functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

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

~~SEC. 10.~~

SEC. 11. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) A prescriber shall not dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon, *if applicable*, a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

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

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

~~SEC. 11.~~

SEC. 12. 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 5

Nicotine Replacement Products

Martinez, Lori@DCA

Subject: California State Board of Pharmacy Subscriber Alert

NICOTINE REPLACEMENT THERAPY NOW AVAILABLE WITHOUT PRESCRIPTION

Pharmacists Can Furnish Nicotine Replacement Therapy for Smoking Cessation

The California State Board of Pharmacy announces that regulations are now in effect for pharmacists to furnish nicotine replacement therapy (NRT), to assist patients in smoking cessation. The regulation became effective January 25, 2016.

Pharmacists undergo lengthy education in drug therapy. Additionally, pharmacists dispensing the NRT must complete two hours of approved continuing education and ongoing biennial training on NRT.

To provide these services, pharmacists must ask specific questions about a patient's:

- current tobacco use and previous attempts to quit;
- whether she is pregnant or plans to become pregnant;
- heart attack within the last two weeks;
- history of palpitations, irregular heartbeats, or diagnosed with arrhythmia;
- frequent chest pain or diagnosed with unstable angina;
- nasal allergies; and
- diagnosed with temporal mandibular joint (TMJ) dysfunction.

Based on the patient's answers and the pharmacist's professional judgment, the pharmacist may: furnish the NRT; provide the NRT with cautions; and/or refer the patient to a health care professional.

In 2014, nearly 17 out of every 100 US adults smoke cigarettes - - equating to about 40 million adults in the US, according to the CDC. Cigarette smoking is the leading cause of preventable disease and death in the US, accounting for 480,000 deaths every year. Over 16 million Americans live with smoking-related diseases.

Pharmacists obtained authority to provide these services pursuant to SB 493 (Hernandez), which authorizes the furnishing of NRT pursuant to a state protocol developed by the California State Board of Pharmacy and Medical Board of California.

"Quitting smoking is difficult to do, but important to patient health. Pharmacists can now offer greater assistance to individuals who have decided to quit smoking," said California State Board of Pharmacy Executive Officer Virginia Herold.

Click here to view the regulation: http://www.pharmacy.ca.gov/laws_regs/1746_2_ooa.pdf

The CA State Board of Pharmacy protects and promotes the health and safety of California consumers by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement. For more information on the Board of Pharmacy, go to http://www.pharmacy.ca.gov/

Board of Pharmacy
Department of Consumer Affairs

ORDER OF ADOPTION

Adopt §1746.2 of Article 5 of division 17 of Title 16 of the California Code of Regulations to read as follows:

§1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

- (A) Review the patient's current tobacco use and past quit attempts.
- (B) Ask the patient the following screening questions:
  - (i) Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
  - (ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
  - (iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
  - (iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
  - (v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

(vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

(C) When a nicotine replacement product is furnished:

(i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.

(ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.

(D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy's or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(10) Nicotine Replacement Therapy Medications for Smoking Cessation

NICOTINE REPLACEMENT THERAPY MEDICATIONS FOR SMOKING CESSATION

Rx for Change

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY					COMBINATION NRT
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	
PRODUCT	**Nicorette[1], Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge,[1] Nicorette Mini Lozenge,[1] Generic** OTC 2 mg, 4 mg cherry, mint	**NicoDerm CQ[1], Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	**Nicotrol NS[2]** Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	**Nicotrol Inhaler[2]** Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	**Combinations with demonstrated efficacy** Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
PRECAUTIONS	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
DOSING	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	*Reserve for patients smoking ≥10 cigarettes/day:* **Long-acting NRT**: to prevent onset of severe withdrawal symptoms ▪ **Nicotine patch** 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks **PLUS** **Short-acting NRT**: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ **Nicotine gum (2 mg)** 1 piece q 1–2 hours as needed *OR* ▪ **Nicotine lozenge (2 mg)** 1 lozenge q 1–2 hours as needed *OR* ▪ **Nicotine nasal spray** 1 spray in each nostril q 1–2 hours as needed *OR* ▪ **Nicotine inhaler** 1 cartridge q 1–2 hours as needed

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Combination therapy is more costly than monotherapy ▪ See disadvantages listed for individual agents

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

Authority: Sections 4005, 4052(a)(10) and 4052.9, Business and Professions Code. Reference: Sections 4052(a)(10) and §4052.9, Business and Professions Code.

Naloxone Hydrochloride

OVERDOSE RESCUE DRUG NOW AVAILABLE WITHOUT PRESCRIPTION

Pharmacists Can Furnish Naloxone for Opioid Overdose

The California State Board of Pharmacy announces that its final regulations are now in effect for pharmacists to furnish, without a prescription, naloxone (also known as Narcan), an antidote to reverse opioid overdose. The regulation became effective January 27, 2016.

Opioids are narcotic prescription medications, which are prescribed for severe pain. The street drug heroin is also an opioid. National overdose deaths from prescription opioids increased 3.4-fold while deaths from heroin increased 6-fold from 2001 to 2014. According to the CDPH, California deaths involving prescription pain medications have increased 16.5 percent since 2006. From 2008 to 2012, there were 7,428 prescription opioid-related deaths in the state.

In 2012 alone, there were more than 1,800 opioid-related deaths in California and 72 percent of those deaths involved prescription pain medications.

Naloxone is an opioid overdose rescue drug, which will now be available by request or at the suggestion of a pharmacist in California pharmacies. Individuals who themselves are not using prescription drugs may obtain naloxone for use for others in emergencies.

Pharmacists dispensing the potentially life-saving medication must successfully complete one hour of continuing education on all forms of naloxone hydrochloride, screen for any hypersensitivity to naloxone and must provide the recipient with training in opioid overdose prevention, recognition, response and on the administration of naloxone.

Vicodin, Norco, Zohydor, Percocet, OxyContin, Roxicodone, Demerol, Dilaudid, Opana and Suboxone are some common brand name opioids. Generic names of prescription opioid medication include morphine, codeine, hydrocodone, hydromorphone, methadone, oxycodone, fentanyl, buprenorphine and oxymorphone.

Accidentally taking too much of a prescribed opioid, combining it with alcohol or other drugs, or abusing it can lead to overdose, depressed respiration and death.

The new regulation replaces an emergency regulations scheduled to expire April 2016 and updates labeling and training requirements for pharmacists furnishing naloxone.

Naloxone is a non-narcotic, prescription drug that reverses the immediate effects of opiate overdose, but 911 must be called immediately following administration for medical assistance. Naloxone blocks the receptors in the brain from the effects of the opioids and can restore breathing. It may be administered by intramuscular injection, intranasal spray or auto-injector.

Pharmacists' authority to furnish naloxone was established by AB 1535 (Bloom), which was passed in 2014. The law authorized the furnishing of naloxone pursuant to a protocol developed by the Board of Pharmacy and approved by the Medical Board of California.

"Statistics from 2014 continue to show that deaths from prescription drugs continue to claim more lives than motor vehicle accidents," said Board of Pharmacy President Amy Gutierrez. "Pharmacists are well positioned to provide this medication to appropriate recipients," she said.

Click here to view the regulation: http://www.pharmacy.ca.gov/laws_regs/1746_3_ooa.pdf

Click here to view the naloxone fact sheet: http://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf

Click here to view the Board of Pharmacy Prescription Drug Abuse Prevention page and public service announcement video: http://www.pharmacy.ca.gov/consumers/rx_abuse_prevention.shtml

Click here to view AB 1535 (Bloom):
http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140AB1535&search_keywords

For more information on the Board of Pharmacy, go to http://www.pharmacy.ca.gov/.

BOARD OF PHARMACY
ORDER OF ADOPTION

Add and Adopt §1746.3, which is new regulation text, as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

~~(a)~~ A pharmacist furnishing naloxone hydrochloride pursuant to ~~S~~section 4052.01 of the Business and Professions Code shall ~~follow the protocol specified in subdivision (b)~~ satisfy the requirements of this section.

(a) As used in this section:
(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.
(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

~~(b)~~ (c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.
Before providing naloxone hydrochloride, the pharmacist shall:

~~(1) Authority: Section 4052.01(a) of the California Business and Professions Code authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.~~

~~(2) Purpose: To provide access to naloxone hydrochloride via standardized procedures so that pharmacists may educate about and furnish naloxone hydrochloride to decrease harm from opioid[1] overdose.~~

~~(3) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:~~

~~[1] For purposes of this protocol, "opioid" is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.~~
~~[2] These screening questions shall be made available in alternate languages for patients whose primary language is not English.~~
~~[3] For purposes of this protocol, "recipient" means the person to whom naloxone hydrochloride is furnished.~~

~~(A)~~ (1) Screen ~~for the following conditions~~ the potential recipient by asking the following questions:[2]

~~(i.)~~ (A) Whether the potential recipient[3] currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B. ~~ii and continue with Procedure~~);

~~(ii.)~~ (B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue. ~~with Procedure~~);

~~(iii.)~~ (C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone.[2] (If the recipient answers yes, the pharmacist may not provide naloxone. ~~do not furnish~~ If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

~~(B)~~ (2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

~~(C)~~ (3) When naloxone hydrochloride is furnished:

~~(i.)~~ (A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

~~(ii.)~~ (B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

~~(iii.)~~ (C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: ~~Naloxone hydrochloride may be supplied as an intramuscular injection, intranasal spray, and auto-injector. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.~~ A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA- approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

~~(5) Suggested Kit Labeling:~~

~~Intramuscular~~	~~Intranasal~~	~~Auto-Injector~~
~~Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration.~~ ~~Kit should contain 2 vials and 2 syringes.~~	~~Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.~~ ~~Kit should contain 2 prefilled needleless syringes and 2 atomizers.~~	~~Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Kit is commercially available as a twin pack with directions for administration included.~~

~~Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.~~

~~Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy website.~~

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data ~~processing~~ or manual record mode such that the required information under title 16, sections ~~1717 and~~ 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

~~(9) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.~~

~~(10)~~ (9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority ~~and Reference~~: Section 4052.01, Business and Professions Code.
Reference: Section 4052.01, Business and Professions Code.

Attachment 6

Self-Administered Hormonal Contraception

BOARD OF PHARMACY
Department of Consumer Affairs

ORDER OF ADOPTION

Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;
(B) Transdermal;
(C) Vaginal;
(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;
(B) Review the self-screening answers and clarify responses if needed;
(C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in

administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
    (i) Dosage;
    (ii) Effectiveness;
    (iii) Potential side effects;
    (iv) Safety;
    (v) The importance of receiving recommended preventative health screenings;
    (vi) That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care

provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program

completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2a	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
2b	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
2c	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19a	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
19b	If yes, list them here:		

20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

Authority: Sections 4005, 4052, and 4052.3, Business and Professions Code.
Reference: Sections 4022, 4052, 4052.3, 4052.9, 4081, 4103, 4105, 4231, and 4232 Business & Professions Code.

Self-Assessments

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. 01/11)~~ (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self- Assessment" and on Form 17M-14 ~~(Rev. 01/11)~~ (Rev. 10/14) 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.

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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 and retained in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, ~~a~~ 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. ~~1/11~~ 02/12).

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: _____

~~or~~ Accredited by (optional): _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays ~~Daily~~* _____ *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=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APP # _____ 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

12. _____ TCH # _____ Exp. Date: _____
_____
_____

13. _____ TCH # _____ Exp. Date: _____
_____
_____

14. _____ TCH # _____ Exp. Date: _____

15. _____ 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. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)
☐	☐	☐	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])
☐	☐	☐	1.9. 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)
☐	☐	☐	1.10. Does the pharmacy compound sterile ~~injectable~~ drugs? (If yes, complete ~~section~~ ~~24~~ section 27 – "Compounding.")

PIC Initials

Yes No N/A

☐☐☐ 1.11. 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. 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. The pharmacy reports to the board within 14 ~~30~~ days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ 1.14. 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. 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: _____

_____

PIC Initials

2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed ~~premise~~ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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 of this Self-Assessment.)

~~4.~~ 5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ ~~4.1.~~ 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)

~~Yes No N/A~~

☐☐☐ ~~4.2.~~ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

☐☐☐ ~~4.3.~~ 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)

☐☐☐ ~~4.4.~~ 5.4. Is the PIC in charge of another pharmacy?

☐☐☐ ~~4.5.~~ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ ~~4.6.~~ 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)

☐☐☐ ~~4.7.~~ 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. 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: _____

_____

PIC Initials

~~5.~~ 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)
☐	☐	☐	~~5.1.~~ 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 ~~per formed~~ 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))
☐	☐	☐	~~5.2.~~ 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 access 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)
☐	☐	☐	~~5.3.~~ 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: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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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. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

- ☐ 7.2.1 Perform 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 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ 7.2.3 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])
- ☐ 7.2.4 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])
- ☐ 7.2.5 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])
- ☐ 7.2.6 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])

~~6.~~ 8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ ~~6.1.~~ 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)

PIC Initials

Yes No N/A

☐☐☐ ~~6.2.~~ 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)

☐☐☐ ~~6.3.~~ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (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])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~7.~~ 9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ ~~7.1.~~ 9.1. Registered pharmacy technicians are performing 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)

☐☐☐ ~~7.2.~~ 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])

☐☐☐ ~~7.3.~~ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~7.4.~~ 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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~~8.~~ 10. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ ~~8.1.~~ 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)

☐☐☐ ~~8.2.~~ 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

~~9.~~ 11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ ~~9.1.~~ 11.1. Pharmacists provide oral consultation: (B&PC 4052[a][7], CCR 1707.2)~~:~~

- ☐ ~~9.1.1.~~ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ ~~9.1.2.~~ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ ~~9.1.3.~~ 11.1.3. upon request; and
- ☐ ~~9.1.4.~~ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.

☐☐☐ ~~9.2.~~ 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)

☐☐☐ ~~9.3.~~ 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ ~~9.4.~~ 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])

☐☐☐ ~~9.5.~~ 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ ~~9.6.~~ 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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~~10.~~ 12. Prescription Requirements

Yes	No	N/A	
☐	☐	☐	~~10.1.~~ 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)
☐	☐	☐	~~10.2.~~ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the ~~direction~~ direct supervision of a pharmacist. (B&PC 4070, CCR 1717)
☐	☐	☐	~~10.3.~~ 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)
☐	☐	☐	~~10.4.~~ 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)
☐	☐	☐	~~10.5.~~ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])
☐	☐	☐	~~10.6.~~ 12.6. Facsimile prescriptions are received only from a prescriber's office. (B&PC 4040[c])
☐	☐	☐	~~10.7.~~ 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])
☐	☐	☐	~~10.8.~~ 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)
☐	☐	☐	~~10.9.~~ 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~11.~~ 13. Prescription Labeling, Furnishing and Dispensing

Yes	No	N/A	
☐	☐	☐	~~11.1.~~ 13.1. The prescription label contains all the required information. (B&PC 4076)
☐	☐	☐	~~11.2.~~ 13.2. The prescription label is formatted in accordance with CCR 1707.5.
☐	☐	☐	~~11.3.~~ 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])

PIC Initials

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 13.3.1; (CCR 1707.5[a][2])
- ☐ 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])

☐☐☐ ~~11.4.~~ 13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: _____ to _____

☐☐☐ ~~11.5.~~ 13.6. Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)

☐☐☐ ~~11.6.~~ 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])

☐☐☐ ~~11.7.~~ 13.8. Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ ~~11.8.~~ 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. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ ~~11.9.~~ 13.10. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ ~~11.10.~~ 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. (~~25~~15 USC 1473~~ section 4~~[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ ~~11.11.~~ 13.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ ~~11.12.~~ 13.13. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ ~~11.13.~~ 13.14. ~~This~~ 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 .

☐☐☐ ~~11.14.~~ 13.15. 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)

PIC Initials

Yes No N/A

☐☐☐ ~~11.15.~~ 13.16. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

☐☐☐ 13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

☐ 13.17.1 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])

☐ 13.17.1.1 The prescriber has not indicated "no change to quantity" or words of similar meaning; (B&PC 4064.5[d])

☐ 13.17.1.2. 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])

☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13.17.1.4. 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])

☐ 13.17.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐☐☐ 13.18. 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])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~12.~~ 14. Refill Authorization

Yes No N/A

☐☐☐ ~~12.1.~~ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ ~~12.2.~~ 14.2. Refills are documented. (CCR 1717)

☐☐☐ ~~12.3.~~ 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)

☐☐☐ ~~12.4.~~ 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

PIC Initials

Yes No N/A

☐☐☐ ~~12.5.~~ 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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~~13.~~ 15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ ~~13.1.~~ 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)

☐☐☐ ~~13.2.~~ 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ ~~13.3.~~ 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])

☐☐☐ ~~13.4.~~ 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])

☐☐☐ ~~13.5.~~ 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ ~~13.6.~~ 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ☐ ~~13.6.1.~~ 15.6.1. Date, location, and participants in the quality assurance review;
- ☐ ~~13.6.2.~~ 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ ~~13.6.3.~~ 15.6.3. Findings and determinations; and
- ☐ ~~13.6.4.~~ 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ ~~13.7.~~ 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])

☐☐☐ ~~13.8.~~ 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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~~14.~~ 16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ ~~14.1.~~ 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])

~~Yes No N/A~~

☐☐☐ ~~14.2.~~ 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)

☐☐☐ ~~14.3.~~ 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])

☐☐☐ 16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])

☐☐☐ 16.5. 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: _____

_____

~~15.~~ 17. Prescription Transfer

Yes No N/A

☐☐☐ ~~15.1.~~ 17.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

☐☐☐ ~~15.2.~~ 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

☐☐☐ ~~15.3.~~ 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])

Yes No N/A

☐☐☐ ~~15.4.~~ 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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~~16.~~ 18. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ ~~16.1.~~ 18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ ~~16.2.~~ 18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

~~Yes No N/A~~

☐☐☐ ~~16.3.~~ 18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ ~~16.4.~~ 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])

☐☐☐ ~~16.5.~~ 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)

☐☐☐ ~~16.6.~~ 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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~~17.~~ 19. Record Keeping Requirements

Yes No N/A

☐☐☐ ~~17.1.~~ 19.1. A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ ~~17.2.~~ 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):

- ☐ ~~17.2.1.~~ 19.2.1. Prescription records (B&PC 4081[a])
- ☐ ~~17.2.2.~~ 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- ☐ ~~17.2.3.~~ 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ☐ ~~17.2.4.~~ 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

PIC Initials

☐ ~~17.2.5.~~ 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ ~~17.2.6.~~ 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ ~~17.2.7.~~ 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ ~~17.2.8.~~ 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

☐☐☐ ~~17.3.~~ 19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC ~~4140, 4149~~ 4145.5)

☐ ~~17.3.1.~~ 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;

☐ ~~17.3.2.~~ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

☐ ~~17.3.3.~~ 19.3.3. The sale of ~~10 or fewer~~ 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)

☐ ~~17.3.4.~~ 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)

☐ ~~17.3.5.~~ 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.

☐☐☐ ~~17.4.~~ 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)

☐☐☐ 19.6. The pharmacy dispenses epinephrine auto-injector to 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)

☐ 19.6.1.A physician/surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119.3[a][1])

PIC Initials

☐ 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])

☐ 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~18.~~ 20. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

☐☐☐ ~~18.1.~~ 20.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[b])

☐☐☐ ~~18.2.~~ 20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

☐☐☐ ~~18.3.~~ 20.3. 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])

☐☐☐ ~~18.4.~~ 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])

☐☐☐ ~~18.5.~~ 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])

~~Yes No N/A~~

☐☐☐ ~~18.6.~~ 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)

☐☐☐ ~~18.7.~~ 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)

☐☐☐ ~~18.8.~~ 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)

PIC Initials

Yes No N/A

☐☐☐ ~~18.9.~~ 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)

☐☐☐ ~~18.10.~~ 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)

☐☐☐ ~~18.11.~~ 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])

☐☐☐ ~~18.12.~~ 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.

☐☐☐ ~~18.13.~~ 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)

☐☐☐ ~~18.14.~~ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ ~~18.15.~~ 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])

☐☐☐ ~~18.16.~~ 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

~~19.~~ 21. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ ~~19.1.~~ 21.1. A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ ~~19.2.~~ 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.~~ form, and: ~~The licensed facility provides the pharmacy with a copy of the prescriber signed order when available.~~ (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)

~~☐☐☐ 19.3. An electronically transmitted order 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 after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5)~~

☐☐☐ ~~19.4.~~ 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])

☐☐☐ ~~19.5.~~ 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)

☐☐☐ ~~19.6.~~ 21.5. 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)

☐☐☐ ~~19.7.~~ 21.6. 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

Yes No N/A

☐☐☐ ~~19.8.~~ 21.7. 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])

☐☐☐ ~~19.9.~~ 21.8. 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~~

☐☐☐ ~~19.10.~~ 21.9. 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. 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. 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. 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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~~20.~~ 22. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ ~~20.1.~~ 22.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ ~~20.2.~~ 22.2. 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)

☐☐☐ ~~20.3.~~ 22.3. 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:

- ☐ ~~20.3.1.~~ 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])
- ☐ ~~20.3.2.~~ 22.3.2. A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

PIC Initials

☐ ~~20.3.3.~~ 22.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

Yes No N/A

☐☐☐ ~~20.4.~~ 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:

☐ ~~20.4.1.~~ 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])

☐ ~~20.4.2.~~ 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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~~21.~~ 23. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ ~~21.1.~~ 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)

☐☐☐ ~~21.2.~~ 23.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐☐☐ ~~21.3.~~ 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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~~22.~~ 24. Refill Pharmacy

Yes No N/A

☐☐☐ ~~22.1.~~ 24.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ ~~22.2.~~ 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)

☐☐☐ ~~22.3.~~ 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.

Yes No N/A

☐☐☐ ~~22.4.~~ 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])

☐☐☐ ~~22.5.~~ 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])

☐☐☐ ~~22.6.~~ 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])

☐☐☐ ~~22.7.~~ 24.7. Both pharmacies maintain complete and accurate records ~~or~~ of refill. (CCR 1707.4[a][4])

☐☐☐ ~~22.8.~~ 24.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ ~~22.9.~~ 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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25. 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])

PIC Initials

☐ 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])

~~23.~~ 26. Policies and Procedures

Yes No N/A

☐☐☐ ~~23.1.~~ 26.1. There are written policies and procedures in place for:

☐ ~~23.1.1.~~ 26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order; (B&PC 4052.1[a][3])

☐ ~~23.1.2.~~ 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~~ 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])

PIC Initials

☐ ~~23.1.3.~~ 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])

☐ ~~23.1.4.~~ 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])

☐ ~~23.1.5.~~ 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])

☐ ~~23.1.6.~~ 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])

☐ ~~23.1.7.~~ 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])

☐ ~~23.1.8.~~ 26.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ ~~23.1.9.~~ 26.1.9. Reporting requirements to protect the public; (B&PC 4104)

☐ ~~23.1.10.~~ 26.1.10. Preventing the dispensing of a prescription drug that is contrary to the law~~;~~. (B&PC 733)

☐ ~~23.1.11.~~ 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)

☐ ~~23.1.12.~~ 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)

Yes No N/A

☐☐☐ ~~23.2.~~ 26.2. Does your pharmacy employ the use of a common electronic file?

☐ 23.2.1. 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)

PIC Initials

☐ 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])

☐ 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.

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~COMPOUNDING~~

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. ~~01/11~~ 02/12) (CCR 1735.2[j])

PIC Initials

~~25.~~ 28. ~~NUCLEAR PHARMACY~~ Nuclear Pharmacy

Yes No N/A

☐☐☐ ~~25.1.~~ 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)

☐☐☐ ~~25.2.~~ 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)

☐☐☐ ~~25.3.~~ 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. ~~01/11~~ 02/12.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

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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])

PIC Initials

☐ 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: _____

☐☐☐ 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])

PIC Initials

☐☐☐ 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])

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])

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 PHARMACY OWNER OR 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 _____

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 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:
Law-Tech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: 877-508-6704

CURES
4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

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) 322-3350
Fax: (916) 574-7697
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
2500 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

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

DEA Registration Support (all of CA):
(800) 882-9539

Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

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 - 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 – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

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 – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

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

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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. ~~01/11~~ 10/14) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~01/11~~ 02/12).)

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: _____

~~or~~ Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: ~~*Daily*~~ *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 # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
2. _____	RPH # _____	Exp. Date: _____
	APP # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
3. _____	RPH # _____	Exp. Date: _____
	APP # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
4. _____	RPH # _____	Exp. Date: _____
	APP # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
5. _____	RPH # _____	Exp. Date: _____
	APP # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
6. _____	RPH # _____	Exp. Date: _____
	APP # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
7. _____	RPH # _____	Exp. Date: _____
	APP # _____	Exp. Date: _____
	DEA # _____	Exp. Date: _____
8. _____	RPH # _____	Exp. Date: _____
	APP # _____	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: _____

_____
PIC
Initials

~~17. _____ TCH # _____ Exp. Date: _____~~

~~18. _____ TCH # _____ Exp. Date: _____~~

_____
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 ~~30~~ 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)

_____
PIC Initials

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 ~~injectable~~ drugs?
(If yes, complete section ~~24~~ 27 – "Compounding ~~Sterile Injectable Drugs~~")

☐☐☐ 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: _____

_____

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])

~~Yes No N/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])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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])

_____
PIC Initials

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])
- ☐ 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])

~~5.~~ 6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ ~~5.1.~~ 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)

☐☐☐ ~~5.2.~~ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy ~~(CCR 1709.2[b])~~ (CCR 1709.1[b])

☐☐☐ ~~5.3.~~ 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 _____

☐☐☐ ~~5.4.~~ 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)

☐☐☐ ~~5.5.~~ 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: _____

_____

~~6.~~ 7. Duties of a Pharmacist

Yes No N/A

☐☐☐ ~~6.1.~~ 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 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)

☐☐☐ ~~6.2.~~ 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. (B&PC 4027, 4051, 4052, 4052.2)

_____
PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

- ☐ 8.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ 8.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ 8.2.3 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])
- ☐ 8.2.4 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])
- ☐ 8.2.5 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])
- ☐ 8.2.6 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])

~~7.~~ 9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ ~~7.1.~~ 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)

- ☐ 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]

☐☐☐ ~~7.2.~~ 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])

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PIC Initials

Yes No N/A

☐☐☐ ~~7.3.~~ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~8.~~ 10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ ~~8.1.~~ 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)

☐☐☐ ~~8.2.~~ 10.2. 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, 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])

☐☐☐ ~~8.3.~~ 10.3. 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)

☐☐☐ ~~8.4.~~ 10.4. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~8.5.~~ 10.5. 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)

~~Yes No N/A~~

☐☐☐ ~~8.6.~~ 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

☐☐☐ 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])

☐☐☐ ~~8.7.~~ 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)

- ☐ ~~8.7.1.~~ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ ~~8.7.2.~~ 10.8.2. Compounded or repackaged products are previously checked by a ~~pharmacist.~~ pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ ~~8.7.3.~~ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.

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☐ ~~8.7.4.~~ 10.8.4. The pharmacy technician ~~check~~ checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.

☐ ~~8.7.5.~~ 10.8.5. There is an ongoing evaluation of the program that uses ~~specially~~ specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

Yes No N/A

☐☐☐ 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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~~9.~~ 11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ ~~9.1.~~ 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)

☐☐☐ ~~9.2.~~ 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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PHARMACY PRACTICE

~~10.~~ 12. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ ~~10.1.~~ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

☐ ~~10.1.1.~~ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;

☐ ~~10.1.2.~~ 12.1.2. Repackaging and compounding records;

☐ ~~10.1.3.~~ 12.1.3. Physician orders;

☐ ~~10.1.4.~~ 12.1.4. Wards, nursing stations and night stock medications;

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☐ ~~10.1.5.~~ 12.1.5. Drugs brought into the facility by patients for storage or use;

☐ ~~10.1.6.~~ 12.1.6. Bedside medications;

☐ ~~10.1.7.~~ 12.1.7. Emergency drug supply;

☐ ~~10.1.8.~~ 12.1.8. Pass medications;

☐ ~~10.1.9.~~ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;

☐ ~~10.1.10.~~ 12.1.10. Routine distribution of inpatient medications;

☐ ~~10.1.11.~~ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;

☐ ~~10.1.12.~~ 12.1.12. Handling of medication when pharmacist not on duty; and

☐ ~~10.1.13.~~ 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

☐☐☐ ~~10.2.~~ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

☐ ~~10.2.1.~~ 12.2.1. Destruction of controlled substances; and

☐ ~~10.2.2.~~ 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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~~11.~~ 13. Medication/Chart Order

Yes No N/A

☐☐☐ ~~11.1.~~ 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)

☐☐☐ ~~11.2.~~ 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])

☐☐☐ ~~11.3.~~ 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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PIC Initials

~~12.~~ 14. Labeling and Distribution

Yes No N/A

☐☐☐ ~~12.1.~~ 14.1. Unit dose medication and parenteral admixtures 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 1751.2)

☐☐☐ ~~12.2.~~ 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]).

☐☐☐ ~~12.3.~~ 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 ~~received~~ 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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~~13.~~ 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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~~14.~~ 16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ ~~14.1.~~ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ ~~14.2.~~ 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.)

☐☐☐ ~~14.3.~~ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

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Yes No N/A

☐☐☐ ~~14.4.~~ 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)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~15.~~ 17. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ ~~15.1.~~ 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)

☐☐☐ ~~15.2.~~ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ ~~15.3.~~ 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])

☐☐☐ ~~15.4.~~ 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])

~~Yes No N/A~~

☐☐☐ ~~15.5.~~ 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ ~~15.6.~~ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

- ☐ ~~15.6.1.~~ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ ~~15.6.2.~~ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ ~~15.6.3.~~ 17.6.3. Findings and determinations;
- ☐ ~~15.6.4.~~ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ ~~15.7.~~ 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])

☐☐☐ ~~15.8.~~ 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: _____

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PIC Initials

~~16.~~ 18. Record Keeping Requirements

Yes No N/A

☐☐☐ ~~16.1.~~ 18.1. A completed biennial pharmacy self -assessment is on file in the pharmacy and is maintained for three years. (CCR 1715)

☐☐☐ ~~16.2.~~ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

- ☐ ~~16.2.1.~~ 18.2.1. Prescription records (B&PC 4081[a])
- ☐ ~~16.2.2.~~ 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- ☐ ~~16.2.3.~~ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ ~~16.2.4.~~ 18.2.4. U.S. Official Order Forms (DEA Form~~-~~ 222) (21 CFR 1305.13)
- ☐ ~~16.2.5.~~ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- ☐ ~~16.2.6.~~ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ ~~16.2.7.~~ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- ☐ ~~16.2.8.~~ 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).

☐☐☐ ~~16.3.~~ 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)

~~Yes No N/A~~

☐☐☐ ~~16.4.~~ 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)

☐☐☐ ~~16.5.~~ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

☐☐☐ ~~16.6.~~ 18.6. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ ~~16.7.~~ 18.7. 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)

☐☐☐ ~~16.8.~~ 18.8. DEA Forms 222 are properly executed. (21 CFR ~~1305.09)~~ 1305.12)

☐☐☐ ~~16.9.~~ 18.9. 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 ~~1309.09)~~ 1305.13)

☐☐☐ ~~16.10.~~ 18.10. 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)

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PIC Initials

Yes No N/A

☐☐☐ ~~16.11.~~ 18.11. 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)

☐☐☐ ~~16.12.~~ 18.12. Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ ~~16.13.~~ 18.13. 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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~~17.~~ 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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~~18.~~ 20. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ ~~18.1.~~ 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])

☐☐☐ ~~18.2.~~ 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])

☐☐☐ ~~18.3.~~ 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])

☐☐☐ ~~18.4.~~ 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])

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PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~19.~~ 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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~~20.~~ 22. Emergency Room Dispensing

Yes No N/A

☐☐☐ ~~20.1.~~ 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])~~:~~

- ☐ ~~20.1.1.~~ 22.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ ~~20.1.2.~~ 22.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ ~~20.1.3.~~ 22.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ ~~20.1.4.~~ 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;
- ☐ ~~20.1.5.~~ 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
- ☐ ~~20.1.6.~~ 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;

~~**Yes No N/A**~~

☐☐☐ ~~20.2.~~ 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])

☐☐☐ ~~20.3.~~ 22.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

Yes No N/A

☐☐☐ ~~20.4.~~ 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)

☐☐☐ ~~20.5.~~ 22.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

☐☐☐ ~~20.6.~~ 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)

☐☐☐ ~~20.7.~~ 22.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~21.~~ 23. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ ~~21.1.~~ 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)

☐☐☐ ~~21.2.~~ 23.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ ~~21.3.~~ 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)

☐☐☐ ~~21.4.~~ 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])

☐☐☐ ~~21.5.~~ 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: _____ to _____

~~Yes No N/A~~

☐☐☐ ~~21.6.~~ 23.6. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ ~~21.7.~~ 23.7. 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)

☐☐☐ ~~21.8.~~ 23.8. 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)

☐☐☐ ~~21.9.~~ 23.9. 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)

☐☐☐ ~~21.10.~~ 23.10. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

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Yes No N/A

☐☐☐ ~~21.11.~~ 23.11. 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. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ ~~21.12.~~ 23.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~22.~~ 24. ~~Central Fill~~ Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ ~~22.1.~~ 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: _____

☐☐☐ ~~22.2.~~ 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.

☐☐☐ ~~22.3.~~ 24.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ ~~22.4.~~ 24.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ ~~22.5.~~ 24.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ ~~22.6.~~ 24.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ ~~22.7.~~ 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 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): _____

_____
PIC Initials

25.1.4. _____ Distance (miles): _____

☐☐☐ 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 unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient's bedside. The barcode information contains: (B&PC 4128.4)

☐ 25.3.1. The date the medication was prepared.

☐ 25.3.2. The components used in the drug product.

☐ 25.3.3. The lot number or control number.

☐ 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.

☐☐☐ 25.4. The 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. (B&PC 4128.5)

☐☐☐ 25.5. 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: _____

_____

~~23.~~ 26. Policies and Procedures

Yes No N/A

☐☐☐ ~~23.1.~~ 26.1. There are written policies and procedures in place for:

☐ ~~23.1.1.~~ 26.1.1.The assurance that each patient received information regarding each medication given at the time of discharge.

☐ ~~23.1.2.~~ 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])

☐ ~~23.1.3.~~ 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])

☐ ~~23.1.4.~~ 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])

☐ ~~23.1.5.~~ 26.1.5. Reporting to the board within ~~30~~ 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].

_____
PIC Initials

☐ ~~23.1.6.~~ 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])

☐ ~~23.1.7.~~ 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])

☐ ~~23.1.8.~~ 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])

☐ ~~23.1.9.~~ 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: _____

_____

~~24.~~ 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. ~~01/11~~ 02/12). (CCR 1735.2[j])

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

Pharmacy Law may be obtained by contacting:
LawTech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
http://www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: (877) 508-6704

CURES
P.O. Box 160447
Sacramento, CA 95816-1089
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

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: (877) 729-7789
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) 322-3350
Fax: (916) 574-7697
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

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
DEA Registration Support (all of CA):
(800) 882-9539
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

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 - 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 – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900

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 – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

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. 01/11)~~ (Rev. 10/14) 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, California 95834
(916) 574-7900 FAX (916) 574-8618

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES
SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page ~~18~~ 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 ~~(optional)~~ _____

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: ~~Daily~~Weekdays _____Sat_____ Sun_____ 24 Hours ○

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License #_____ Expiration Date_____

Website Address (optional):_____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ DR#/RPH#_____Exp. Date _____

2. _____ DR#/RPH#_____Exp. Date _____

3. _____ DR#/RPH#_____Exp. Date _____

4. _____ DR#/RPH#_____Exp. Date _____

5. _____ DR#/RPH#_____Exp. Date _____

6. _____ DR#/RPH#_____Exp. Date _____

7. _____ DR#/RPH#_____Exp. Date _____

8. _____ DR#/RPH#_____Exp. Date _____

9. _____ DR#/RPH#_____Exp. Date _____

10_____ DR#/RPH#_____Exp. Date _____

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~~ (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])

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~~ (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, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.8. The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.9. The facility 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 _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 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.

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)

~~Yes No N/A~~

☐ ☐ ☐ 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 ~~11~~ 12 of this document.

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)

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 ~~11~~ 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])

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). ~~Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.~~

Yes No N/A

☐ ☐ ☐ 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)

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 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 ~~11~~ 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])

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])

~~9.~~ 10. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ ~~9.1.~~ 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])

☐ ☐ ☐ ~~9.2.~~ 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])

~~9.3.~~ 10.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

~~10.~~ 11. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ ~~10.1.~~ 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])

Yes No N/A

☐ ☐ ☐ ~~10.2.~~ 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[d])~~ (B&PC 4059.5[d])

☐ ☐ ☐ ~~10.3.~~ 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])

☐ ☐ ☐ ~~10.4.~~ 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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~~11.~~ 12. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ ~~11.1.~~ 12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ ~~11.2.~~ 12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ ~~11.3.~~ 12.3. Are DEA requirements for storage of Schedule ~~III~~ III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

~~Yes No N/A~~

☐ ☐ ☐ ~~11.4.~~ 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])

☐ ☐ ☐ ~~11.5.~~ 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)

☐ ☐ ☐ ~~11.6.~~ 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)

~~11.7.~~ 12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ ~~11.8.~~ 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ ~~11.9.~~ 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)

☐ ☐ ☐ ~~11.10.~~ 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])

☐ ☐ ☐ ~~11.11.~~ 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])

☐ ☐ ☐ ~~11.12.~~ 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])

~~11.13.~~ 12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~11.14.~~ 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])

☐ ☐ ☐ ~~11.15.~~ 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])

☐ ☐ ☐ ~~11.16.~~ 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)

Yes No N/A

☐ ☐ ☐ ~~11.17.~~ 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])

☐ ☐ ☐ ~~11.18.~~ 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)

☐ ☐ ☐ ~~11.19.~~ 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 1309.13[b])~~ (CFR 1305.13[b])

☐ ☐ ☐ ~~11.20.~~ 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])

☐ ☐ ☐ ~~11.21.~~ 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)

☐ ☐ ☐ ~~11.22.~~ 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))

☐ ☐ ☐ ~~11.23.~~ 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 1305.09[d],~~ CFR 1305.17[c], 1305.17[a] [b], and ~~H & S~~ H&SC 11252, 11253, 1304.03)

☐ ☐ ☐ ~~11.24.~~ 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ ~~11.25.~~ 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ ~~11.26.~~ 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])

☐ ☐ ☐ ~~11.27.~~ 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? ~~(CFR 1305.16)~~ (CFR 1305.17[d])

Yes No N/A

☐ ☐ ☐ ~~11.28.~~ 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])

☐ ☐ ☐ ~~11.29.~~ 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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~~12.~~ 13. Policies and Procedures

~~12.1.~~ 13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ ~~12.1.1.~~ 13.1.1. Receipt of drugs~~?~~

☐ ☐ ☐ ~~12.1.2.~~ 13.1.2. Security of drugs~~?~~

☐ ☐ ☐ ~~12.1.3.~~ 13.1.3. Storage of drugs~~?~~ (including maintaining records to document proper storage)

☐ ☐ ☐ ~~12.1.4.~~ 13.1.4. Inventory of drugs~~?~~ (including correcting inaccuracies in inventories)

☐ ☐ ☐ ~~12.1.5.~~ 13.1.5. Distributing drugs~~?~~

☐ ☐ ☐ ~~12.1.6.~~ 13.1.6. Identifying, recording and reporting theft or losses~~?~~

☐ ☐ ☐ ~~12.1.7.~~ 13.1.7. Correcting ~~errors?~~ errors and inaccuracies in inventories~~?~~

Physically quarantining and separating:

☐ ☐ ☐ ~~12.1.8.~~ 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs~~?~~

☐ ☐ ☐ ~~12.1.9.~~ 13.1.9. drugs that have been partially used~~?~~

☐ ☐ ☐ ~~12.1.10.~~ 13.1.10. drugs where the outer or secondary seals on the container have been broken~~?~~

☐ ☐ ☐ ~~12.1.11.~~ 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug~~?~~

☐ ☐ ☐ ~~12.1.12.~~ 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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~~13.~~ 14. Training

Yes No N/A

☐ ☐ ☐ 14.1 ~~Is~~ 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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~~14.~~ 15. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ ~~14.1.~~ 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.

☐ ☐ ☐ ~~14.2.~~ 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])

☐ ☐ ☐ ~~14.3.~~ 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])

☐ ☐ ☐ ~~14.4.~~ 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)

☐ ☐ ☐ ~~14.5.~~ 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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~~15.~~ 16. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ ~~15.1.~~ 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])

☐ ☐ ☐ ~~15.2.~~ 16.2. 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.

☐ ☐ ☐ ~~15.3.~~ 16.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

☐ ☐ ☐ ~~15.4.~~ 16.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

☐ ☐ ☐ ~~15.5.~~ 16.5. 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])

☐ ☐ ☐ ~~15.6.~~ 16.6. Are required records stored off-site only if a board issued written waiver has been granted?

~~15.7.~~ 16.7. 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_____

~~Yes No N/A~~

☐ ☐ ☐ ~~15.8.~~ 16.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ ~~15.9.~~ 16.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ ~~15.10.~~ 16.10. 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])

☐ ☐ ☐ ~~15.11.~~ 16.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

☐ ☐ ☐ ~~15.12.~~ 16.12. 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]):

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~15.13.~~ 16.13. 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)

☐ ☐ ☐ ~~15.14.~~ 16.14. 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])

☐ ☐ ☐ ~~15.15.~~ 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 ~~11~~ 12 of this document.

~~16.~~ 17. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ ~~16.1.~~ 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].

☐ ☐ ☐ ~~16.2.~~ 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])

☐ ☐ ☐ ~~16.3.~~ 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)

☐ ☐ ☐ ~~16.4.~~ 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])

Yes No N/A

☐ ☐ ☐ ~~16.5.~~ 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)

☐ ☐ ☐ ~~16.6.~~ 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])

☐ ☐ ☐ ~~16.7.~~ 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])

☐ ☐ ☐ ~~16.8.~~ 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])

☐ ☐ ☐ ~~16.9.~~ 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])

☐ ☐ ☐ ~~16.10.~~ 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)

☐ ☐ ☐ ~~16.11.~~ 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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~~17.~~ 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 9583~~4~~
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

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

Vaccinations

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 section 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.

Attachment 7

Advanced Practice Pharmacist – 1730, 1730.1, 1749

Title 16. BOARD OF PHARMACY
Second Modified Text

Changes made to the originally proposed language 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 modified proposed language 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.)

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(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 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

For purposes of **Business and Professions Code section** 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) 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) 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(a)(2)(B), an applicant shall provide either:

(1) 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) 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 dates of participation and completion, and area(s) of specialty. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol 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 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 written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B)Completed the required number of hours of clinical services to patients, as specified in this subdivision 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) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) 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 of experience providing clinical services to patients. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 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

Section 100
Requirements

Board of Pharmacy

Proposal to Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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; and make changes to its regulations without regulatory effect pursuant to Title, California Code of Regulations section 100 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 and 4311, Business and Professions Code.

Renewal Requirements

Board of Pharmacy

Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions under ~~$300~~ $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority: Section 4005, Business and Professions Code.
Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

Third Party Logistics Providers

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

1780. Minimum Standards for ~~Wholesalers.~~

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision).

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the wholesaler premises shall be well-lighted.

(d) All materials must be examined upon receipt or before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale and third-party logistics provider drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
(3) Wholesale and third-party logistics provider drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.
Not relevant to third-party logistics providers

1781. Exemption Certificate.
A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's ~~or~~ ,wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

1782. Reporting Sales of Drugs Subject to Abuse.
All manufacturers, ~~and~~ wholesalers and third-party logistics providers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

1783. Manufacturer, ~~or~~ Wholesaler or Third-Party Logistics Provider Furnishing Drugs and Devices.
(a) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to

furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
(c) Dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or~~ wholesaler or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or~~ wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or~~ wholesaler or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.
(d) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.
(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

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

This section will be modified to also establish a self assessment process for the third-party logistics provider by the responsible manager. The changes have not been incorporated below

(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. 01/11) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5,4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.