

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

1706.1 Permit Processing Times

"Permit" as defined by the Permit Reform Act of 1981 means any license, certificate, registration, permit or any other form of authorization required by a state agency to engage in a particular activity or act. Processing times for the board's various programs are set forth below. The actual processing times apply to those persons who take and pass the first available examination.

License or registration type	Maximum Time in Days for Notification That an Application Incomplete or Deficient; and What is Needed to Correct the Deficiency	Maximum Time in Days after Filing a Complete Application in Which the Board Will Notify Applicant of Decision	Actual License or Processing Time in Days Based on Two-Year Compilation
			Min Med Max
Pharmacist License	30	30	67 167 2,192
Foreign Graduate Application	30	30	154 549 1,047
Intern Permit	30	60	1 4 83
Pharmacy Permit	30	60	6 72 305
Clinic Permit	30	60	20 96 325
Non-Resident Pharmacy Permit	30	60	12* 56* 122*
Exemption Certificate	30	60	20 85 185

Hypodermic Distributor's Permit	30	60	7 87 258
Wholesale Drug Permit	30	60	13 88 605
Medical Device Retailer Permit	30	60	
Medical Device Retailer Warehouse Permit	30	60	
Out-of-State Distributor Permit	30	60	1 21 265

*This registration program began January 1, 1989, thus the data are for only one ½ years.

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

1706.2 Abandonment of Application Files

(a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after

being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

(e) An applicant for a intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, 4205 and 4208, Business and Professions Code.

Article 2. Pharmacies

1707. Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall be granted to any entity licensed by the board for off-site storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

(1). The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

(2). The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

(3). The date on which a drug was dispensed or refilled;

(4). The prescription number for each prescription; and

(5). The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authorized cited: Sections 4005, 4121 and 4122, Business and Professions Code. Reference: Sections 4005, 4121 and 4122, Business and Professions Code.

1707.2 Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

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

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with

known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code.

Reference: Sections 4005, 4076 and 4122, Business and Professions Code.

1707.3. Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery.

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

Authority cited: Sections 4005, 4121 and 4122, Business and Professions Code.

Reference: Sections 4005, 4074, 4121 and 4122, Business and Professions Code.

1707.4. Procedures for Refill Pharmacies.

(a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:

(1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.

(2) The prescription container:

(A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and

(B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.

(3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.

(4) Both pharmacies maintain complete and accurate records of the refill, including:

(A) the name of the pharmacist who refilled the prescription;

(B) the name of the pharmacy refilling the prescription; and

(C) the name of the pharmacy that received the refill request.

(5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.

(6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.

(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.

Authority cited: Section 4005, Business & Professions Code. Reference: Sections 4063, 4076, 4081 and 4333, Business & Professions Code.

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

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

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

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.
Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

1707.6 Notice to Consumers

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

1708.2. Discontinuance of Business.

Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4322 and 4333, Business and Professions Code; and 11205, Health and Safety Code.

1708.3. Radioactive Drugs.

A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators

which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

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

1708.4. Pharmacist Handling Radioactive Drugs.

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

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

1708.5. Pharmacy Furnishing Radioactive Drugs.

A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application. A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.

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

1709. Names of Owners and Pharmacist in Charge.

(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the

board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.

(c) The following shall constitute a transfer of permit and require application for a change of ownership: any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license.

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

1709.1. Designation of Pharmacist in Charge.

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

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.

(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.

(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.

(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.

(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305 and 4330, Business and Professions Code.

1710. Hospital Pharmacy.

(a) A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.

(b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:

(1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy,

(2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy,

(3) Each cassette or container meets the requirements of Business and Professions Code section 4076,

(4) Both pharmacies are responsible for ensuring that the order has been properly filled.

(5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.

(6) Prescription information shall be electronically transferred between the two pharmacies.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4029, 4076 and 4380, Business and Professions Code.

1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Section 4125, Business and Professions Code.

1712. Use of Pharmacist Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

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

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

- (9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
- (10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).
- (e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:
- (1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.
 - (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.
 - (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.
 - (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.
 - (5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.
 - (6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.
- (f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.
- (g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

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

1714. Operational Standards and Security.

- (a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.
- (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

Authority cited: Sections 4005 and 4116, Business and Professions Code.

Reference: Sections 4116 and 4117, Business and Professions Code.

1714.1. Pharmacy Operations during the Temporary Absence of a Pharmacist.

This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.

If in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

(b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist.

(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission, and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.

(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours.

(g) For the purposes of this section, ancillary staff includes: an intern pharmacist, a pharmacy technician, non-licensed personnel as defined in Section 1793.3 of Title 16 of the California Code of Regulations and a pharmacy technician trainee as defined in Section 4115.5(a) of the Business and Professions Code.

Authority cited: Sections 4005, 4115 and 4116, Business and Professions Code.
Reference: Sections 4009, 4115, 4115.5 and 4116, Business and Professions Code; and Sections 512 and 1186, Labor Code.

1714.5. Dangerous Drugs and Devices Exempt from the Provisions of Chapter 9, Division 2 of the Business and Professions Code.

As provided in Section 4057 of the Business and Professions Code, the listing below shall be exempt from the provisions of Chapter 9, Division 2 of the Business and Professions Code where the sale or furnishing is made to a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6, of the Welfare and Institutions Code:

- (a) dangerous devices,
- (b) hypodermic needles and syringes,
- (c) sterilized sutures,
- (d) parenteral solutions of 50 cubic centimeters or over,
- (1) sterile water for injection,
- (2) dextrose solutions of 10% or less,

- (3) ready-made parenteral nutritional solutions,
- (4) pre-diluted ready-to-use electrolyte containing solutions,
- (5) colloidal and low molecular weight plasma expanders,
- (6) Mannitol,
- (7) sodium chloride solutions of 5% or less,
- (8) alcohol (ethanol) solutions of 10% or less in dextrose infusions,
- (e) sterile water U.S.P.,
- (f) sterile normal saline solution,
- (g) medicinal gases,
- (h) inhalation anesthetics,
- (i) laboratory chemicals,
- (j) non-controlled topical anesthetics,
- (k) injectable local anesthetics when in sealed, pre-packaged kits,
- (l) topical stains and dyes,
- (m) diagnostic agents and contrast medium for X-ray examination,
- (n) medicated dressings,
- (o) irrigation solutions, and
- (p) ophthalmic irrigation solutions.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4057, Business and Professions Code.

1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new pharmacy permit has been issued, or
 - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
 - (3) There is a change in the licensed location of a pharmacy to a new address.
- (c) The components of this assessment shall be on Form 17M-13 (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment and on Form 17M-14 (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 cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333,

Business and Professions Code, and Sections 1735.2 and 1751. of Title 16 of the California Code of Regulations..

1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions.

The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:

(a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.

(b) The above information shall be provided in the following format:

(1) For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(2) For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or one-half inch nine track magnetic 1600 BPI tape or any other medium approved by the Board of Pharmacy, which diskette, tape or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(3) For each pharmacy without the capacity to comply with either subsection (b)(1) or (2), the original triplicate shall be transmitted to the Department of Justice by the end of the month in which the prescription was filled. For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2).

(4) As to a prescription which is partially filled or dispensed, the period for compliance with subsections (1), (2), or (3) shall be measured from the earlier of the following dates and times: the prescription is either (1) completely dispensed or (2) can no longer be dispensed.

(c) Every pharmacy which has made a submission as required by this section by July 18, 1998, shall receive a reduction of \$75 on its next renewal fee for licensure of the pharmacy by the board. Every pharmacy shall be in compliance with this section and Health and Safety Code section 11165 by September 18, 1998.

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

1715.6. Reporting Drug Loss.

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

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

1716. Variation from Prescriptions.

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4040, Business and Professions Code.

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

- (1) a patient med pak is reused only for the same patient;
- (2) no more than a one-month supply is dispensed at one time; and
- (3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or

herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.25. Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

- (1) Identification of pharmacist(s) transferring information;
- (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
- (3) Original date and last dispensing date;
- (4) Number of refills and date originally authorized;
- (5) Number of refills remaining but not dispensed;
- (6) Number of refills transferred.

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code.
Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

1717.1. Common Electronic Files.

(a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not

required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.

(b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.

(c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.

(d) Common electronic files as authorized by this section shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

(e) Pharmacies maintaining a common electronic file authorized by this section shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

1717.3. Preprinted Multiple Checkoff Prescription Blanks.

(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

(c) "Preprinted multiple checkoff prescription blank," as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription order for that drug.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4040, Business and Professions Code; and Section 11164, Health and Safety Code.

1717.4. Electronic Transmission of Prescriptions.

(a) Except as otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber to the pharmacy.

(b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.

(c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license

classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.

(d) An “interim storage device” means an electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.

(e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.

(f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

(g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.

(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.

1718. Current Inventory Defined.

“Current Inventory” as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081 and 4332, Business and Professions Code.

1718.1. Manufacturer's Expiration Date.

All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed

by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California.

Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005 and 4342, Business and Professions Code.

Article 3. Pharmacist Candidates

1719. Recognized Schools of Pharmacy.

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200 of the Business and Professions Code.

1720. Application for Pharmacist Examination and Licensure.

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.

(b) The fee required by subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.

(c) Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200 and 4200.2, Business and Professions Code.

1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Equivalency Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of at least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 851 and 4200, Business and Professions Code.

1721. Dishonest Conduct during Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall

not be approved to take the examination for three years from the date of the incident, and shall surrender his or her intern license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123, 496 and 4200, Business and Professions Code.

1723.1. Confidentiality of Examination Questions

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, business and Professions Code.

1724. Passing Grade in Pharmacist Examination.

In order to pass the examination, an applicant shall be required to obtain a passing score as determined by a criterion-referenced method of establishing the passing point on each part of the examination. The board may scale the passing score to 75 for the purpose of releasing scores to examinees.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a recognized school of pharmacy.

(b) A final examination must be a part of the course of study.

(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions Code.

1726. Supervision of Intern Pharmacists.

(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.

(b) The pharmacist supervising an intern pharmacist shall provide the experience necessary for the intern pharmacist to become proficient in the practice of pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

1727.1 Intern Pharmacist Address.

The board shall not make an intern pharmacist's address publicly available on the "Internet," as defined by Business and Professions Code section 17538.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, 4030, 4100 and 4208, Business and Professions Code.

1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank-Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4207 and 4208, Business and Professions Code.

1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005, Business and Professions Code.

Reference: Sections 144, 851, and 4200, Business and Professions Code.

Article 3.5. Advanced Practice Pharmacist

1730. Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, subdivision (a)(2)(A).

Note: Authority cited: Sections 4005 and 4210, Business and Professions Code.

Reference: Section 4210, Business and Professions Code.

1730.1. Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsections.

(1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), by providing either:

(A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B), by providing either:

(A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must include no fewer than 1,500 hours of experience providing clinical services to patients. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(A) A written statement from the applicant attesting under penalty of perjury that he or she has:

- (i) Earned the clinical experience within the required time frame; and
- (ii) Completed the required number of hours of experience providing clinical services to patients, as specified in subsection (a)(3).

(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.

(B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least 1,500 hours of experience providing clinical services to patients. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Sections 4005 and 4210, Business and Professions Code.
Reference: Sections 4052.1, 4052.2 and 4210, Business and Professions Code

1730.2. Certification Programs

(a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned.

(b) For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy

Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:

(1) The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;

(2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant's understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;

(3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:

(A) An advanced practice pharmacist licensed by the board or

(B) An expert with experience in the respective area(s) of focus specified in subparagraph (1), where "expert" means a person who qualifies to teach at a school of pharmacy recognized by the board.

(4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and

(5) The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.

Authority cited: Section 4005 and 4210, Business and Professions Code.

Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.

1731. Experimental Programs

In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

(a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.

(b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.

(c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: 5005, 4120, 4161, 4162, 4304 and 4400, Business and Professions Code

Article 4. Continuing Education

1732. Definitions.

As used in this article:

(a) "Accreditation agency" means an organization which evaluates and accredits providers of continuing education for pharmacists.

(b) "Hour" means at least 50 minutes of contact time.

(c) "Provider" means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

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

1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved as accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The Pharmacy Foundation of California.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board; and

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: section 4005, Business and Professions Code. Reference: section 4232, Business and Professions Code.

1732.1. Requirements for Accredited Providers.

(a) No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.

(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.

(c) Providers shall furnish statements of credit to all participants that complete a continuing education course. The statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.

(d) Each provider shall notify the accreditation agency at least 15 days in advance of the first time each new continuing education course is offered or presented.

(e) Providers shall maintain records of completion of their continuing education courses for four years.

(f) Providers shall include the following information in promotional materials regarding continuing education courses:

- (1) Provider's name.
 - (2) The number of hours awarded for completion of the course.
 - (3) The date when the course's accreditation expires.
 - (4) The provider number assigned by the accreditation agency.
 - (5) The name of the provider's accrediting agency.
 - (6) The learning objectives of the program.
 - (7) The nature of the targeted audiences that may best benefit from participation in the program.
 - (8) The speakers and their credentials.
- (g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

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

1732.2. Board Accredited Continuing Education.

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.2, 4202, 4231 and 4232, Business and Professions Code.

1732.3. Requirements for Continuing Education Courses.

(a) Unless denied by the accreditation agency upon audit, all coursework offered by providers may be used to satisfy the continuing education required by section 1732.5 of this Division.

(b) On a random basis or in response to a request by the board, the accreditation agency shall review selected coursework. The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section.

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.

(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:

(A) The scientific knowledge or technical skills required for the practice of pharmacy.

(B) Direct and/or indirect patient care.

(C) The management and operation of a pharmacy practice.

(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

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

1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course, each provider shall submit such materials as are required by the accreditation agency.

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

1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

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

1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for renewal on the grounds of emergency or hardship by applying to the board in writing, setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4234, Business and Professions Code.

1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board.

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

Article 4.5 Compounding

1735. Compounding in Licensed Pharmacies

(a) “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a compounded drug preparation from chemicals or bulk drug substances

(b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1735.1. Compounding Definitions

(a) “Ante-area” means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a

drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02-to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for nonhazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) “Daily” means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) “Displacement airflow method” means a concept which utilizes a low pressure differential high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) “Dosage unit” means a quantity sufficient for one administration to one patient.

(o) “Equipment” means items that must be calibrated, maintained or periodically certified.

(p) “First air” means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) “Gloved fingertip sampling” means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) “Hazardous” means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) “Integrity” means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) “Lot” means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

(u) “Media-fill test” means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins

and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

(y) "Potency" means active ingredient strength within +/-10% (or the range specified in USP37NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) “Strength” means amount of active ingredient per unit of a compounded drug preparation

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1735.2. Compounding Limitations and Requirements; Self-Assessment

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber’s agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber’s office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber’s own veterinary patients seen as part of regular treatment in the prescriber’s office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber’s practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with

pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) 180 days for non-aqueous formulations,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-

numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(I) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1735.3. Recordkeeping of Compounded Drug Preparations

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (I) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispatched CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug product preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1735.4. Labeling of Compounded Drug Preparations

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy -Dispose of Properly” or “Hazardous – Dispose of Properly.”

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

1735.5. Compounding Policies and Procedures

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127, and 4301, Business and Professions Code

1735.6. Compounding Facilities and Equipment

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

1735.7. Training of Compounding Staff

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code

1735.8. Compounding Quality Assurance

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations

shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

Article 5. Dangerous Drugs

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

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

- (1) Muscle relaxants.
- (2) Analgesics with central nervous system depressant effects.
- (3) Antipsychotic drugs including phenothiazines.
- (4) Antidepressants.
- (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V depressant or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.

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

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

- (1) Disulfiram and other drugs (e.g. chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.

1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

1746. Emergency Contraception.

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical

Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse.

Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel.

For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

*Brand Dose Ethinyl Estradiol
per dose (mcg)*

One Tablet Regimens

Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel

Two Tablet Regimens

Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel

Oral Contraceptive Pills

<i>Brand</i>	<i>Tablets per Dose (two doses 12 hours apart*)</i>	<i>Ethinyl Estradiol per dose (mcg)</i>	<i>Levonorgestrel per dose (mg)*</i>
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low- Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri- Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

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

<i>Non-Prescription Drugs</i>	<i>Dose</i>	<i>Timing of Administration</i>
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4052 and 4052.3, Business and Professions Code.

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:

1. Dosage;
2. Effectiveness;
3. Potential side effects;
4. Safety;
5. The importance of receiving recommended preventative health screenings;
6. 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 Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the Food and Drug Administration (FDA). Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) 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 Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration-specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it 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 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	/	
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 <input type="checkbox"/>	No <input type="checkbox"/>
2b	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2c	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
14	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19a	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19b	If yes, list them here:		
20a	Do you have any other medical problems or take regular medication?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
20b	If yes, list them here:		

Authority: Sections 4005 and 4052.3, Business and Professions Code.

Reference: Sections 733, 4052, 4052.3 and 4103, Business and Professions Code.

1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products

Operative January 25, 2016

(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
[See the charts of Nicotine Replacement Therapy Medication for Smoking Cessation at http://www.pharmacy.ca.gov/laws_regs/1746_2_00a.pdf]

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

1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride

Operative January 27, 2016

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall 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.

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

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(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.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. 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.

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

(3) When naloxone hydrochloride is furnished:

(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.

(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.

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

(4) Product Selection: 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) 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 or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(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.

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

1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an approved immunization training program, and
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact

information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e)Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f)Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code, Section 120440, Health and Safety Code, and Sections 300aa – 25, Title 42, United States Code.

Article 6. Fees

1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 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). 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, 4400, 4401 and 4403, Business and Professions Code.

Article 7. Sterile Compounding

1751. Sterile Compounding; Compounding Area; Self-Assessment

(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.

(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:

(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.

(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

(4) There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

1751.1. Sterile Compounding Recordkeeping Requirements.

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

(1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

(6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.2. Sterile Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the labels-for each such preparation:

- (a) The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations administered to inpatients within the hospital.
- (b) Instructions for storage, handling, and administration.
- (c) All hazardous agents shall bear a special label which states “Chemotherapy -Dispose of Properly” or “Hazardous – Dispose of Properly.”

Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

1751.3. Sterile Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

- (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- (2) Airflow considerations and pressure differential monitoring.
- (3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- (4) Cleaning and maintenance of ISO environments and segregated compounding areas.
- (5) Compounded sterile drug preparation stability and beyond use dating.
- (6) Compounding, filling, and labeling of sterile drug preparations.
- (7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- (8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen sterilization methods.

- (2) End-product evaluation, quantitative, and qualitative testing.
- (d) Policies and procedures shall be immediately available to all personnel involved in compounding activities and to board inspectors.
- (e) All personnel involved must read the policies and procedures before compounding sterile drug preparations. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code

1751.4. Facility and Equipment Standards for Sterile Compounding

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

- (1) At the beginning of each shift;
- (2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- (3) After each spill; and
- (4) When surface contamination is known or suspected.

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no

less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section

505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous

compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Authority Cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

1751.5. Sterile Compounding Attire.

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the

method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

(5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.6 Sterile Compounding Consultation; Training of Sterile Compounding Staff

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations.

(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their

assigned tasks properly. This program of training and performance evaluation must address at least the following:

- (A) Aseptic technique.
- (B) Pharmaceutical calculations and terminology.
- (C) Sterile preparation compounding documentation.
- (D) Quality assurance procedures.
- (E) Aseptic preparation procedures.
- (F) Proper hand hygiene, gowning and gloving technique.
- (G) General conduct in the controlled area (aseptic area practices).
- (H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.7. Sterile Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The quality assurance program shall include at least the following:

- (1) Procedures for cleaning and sanitization of the sterile preparation area.
- (2) Actions to be taken in the event of a drug recall.
- (3) Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same

manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were

previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all

ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an “immediate use” preparation. A PEC used solely to compound ‘immediate use’ preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such “immediate use” preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer’s specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer’s specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.10 Sterile Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

REFERENCED TITLE 24, PART 2, CHAPTER 12, REGULATIONS

1250.4 Compounding Area for Parenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room.
2. Have non-porous and cleanable surfaces, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solution. There shall be sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials.
4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.
5. Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:
 - 5.1 An ISO class laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
 - 5.2 An ISO class 5 cleanroom.
 - 5.3 A barrier isolator that provides an ISO class 5 environment for compounding.

Note: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

505.5 Pharmacies: Compounding Area for Parenteral Solutions.

The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

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

505.5.1 Pharmacies: Laminar Flow Biological Safety Cabinet.

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

Article 7.5 Furnishing for Home Administration

1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

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

1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

- (1) furnished by a registered pharmacist;
- (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;
- (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;
- (4) labeled on the outside of the container with a list of the contents;
- (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

- (1) 100mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with

a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Authority cited: Sections 4005 and 4057, Business and Professions Code.

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

1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1753.

Authority cited: Sections 4005 and 4057, Business and Professions Code.

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

Article 8. Prohibitions and Discipline

1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 10/2007), which are hereby incorporated by reference. Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular

case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

1761. Erroneous or Uncertain Prescriptions.

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 11153, Health and Safety Code.

1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(c) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Note: Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

1764. Unauthorized Disclosure of Prescriptions.

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the

prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4040 and 4301, Business and Professions Code.

1765. Commissions, Gratuities, and Rebates.

An unlawful commission, gratuity or rebate prescribed by this article and Business and Professions Code Section 650 includes the rendering by a pharmacist or pharmacy of consultant pharmaceutical services such as those required pursuant to Title 22, Division 5, Chapters 3 and 4 (skilled nursing facilities and intermediate care facilities) to a licensed health care facility for no cost, nominal cost, or below reasonable cost, if that pharmacist or pharmacy obtains patients, clients or customers and/or their prescription orders from that licensed facility or entity. The determination of the value of consultant pharmaceutical services rendered shall include, but not be limited to, the value of all goods and services furnished by the pharmacist or pharmacy to a licensed health care facility.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 650 and 4301, Business and Professions Code.

1766. False or Misleading Advertising.

No pharmacist or permit holder shall violate Section 17500 of the Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 651, 4301 and 17500, Business and Professions Code.

1768. Denial of Application--Reapplication.

(a) Where the board has denied an application for a license, the earliest date on which the applicant may reapply for a license is one year after the effective date of the denial.

(b) All competent evidence of rehabilitation presented will be considered upon a reapplication. The board shall use the criteria listed in section 1769 when considering evidence of rehabilitation.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 480, 486 and 489, Business and Professions Code.

1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An

applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

(c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

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

Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

1770. Substantial Relationship Criteria.

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

Authority cited: Sections 481, 4005, Business and Professions Code.
Reference: Sections 4300, 4309 and 4301, Business and Professions Code.

1771. Posting of Notice of Suspension.

Any holder of a pharmacy permit whose permit is suspended shall post a notice provided by the Board of the Board's suspension order in a location conspicuous to the public. Such notice shall remain posted during the entire period of actual suspension. Failure to post the notice of suspension as required herein shall be a ground for further disciplinary action.

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

1772. Disciplinary Condition of Suspension.

Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of licensure suspension shall not enter any pharmacy prescription area or engage in any pharmacy-related service.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

1773. Disciplinary Conditions of Probation of Pharmacist.

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

(1) Obey all laws and regulations substantially related to the practice of Pharmacy;

(2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;

(3) Submit to peer review if deemed necessary by the Board;

(4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;

(5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.

(6) Not supervise any registered interns nor perform any of the duties of a preceptor;

(7) The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.

(b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;

(1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;

(2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;

(3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;

(4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.

(5) Complete an ethics course that meets the requirements of section 1773.5

(c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

1773.5 Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

(a) The board will consider for approval an ethics course that at minimum satisfies the following requirements:

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The course shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.

(9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

1774. Disciplinary Conditions of Probation of Permit.

(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:

(1) Obey all laws and regulations substantially related to the practice of pharmacy;

(2) The permit, through its officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;

(3) Cooperate with the Board in its inspectional program;

(4) Post or circulate notice of conditions of probation so that they are available to all employees involved in pharmacy operations;

(5) Submit the operation of the pharmacy to peer review if deemed necessary by the Board;

(6) Provide evidence that owners or officers are knowledgeable in the laws pertaining to pharmacy if deemed necessary by the Board.

(b) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Article 9. Citations and Fines

1775. Issuing Citations.

(a) The executive officer or his/her designee may issue a citation which may contain either or both an administrative fine and an order of abatement for:

(1) A violation of the Pharmacy Law (Business and Professions Code 4000 et seq.).

(2) A violation of a regulation adopted by the board.

(3) A violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

(4) Defaulting on a United States Department of Health and Human Services education loan.

(5) A violation of other statutes or regulations for which the board may issue a citation.

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. If a hearing is not requested pursuant to this article, payment of any fine shall not constitute an admission of the violation charged.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148 and 685, Business and Professions Code; and Section 56.36, Civil Code.

1775.1. Amount of Fines.

(a) The fine for violating the Pharmacy Law or regulations adopted pursuant thereto shall not exceed the amount specified in Section 125.9 of the Business and Professions Code, except for a fine issued pursuant to Section 4067 or Section 4127.4 of the Business and Professions Code.

(b) The fine for violating the Confidentiality of Medical Information Act shall not exceed the amount specified in Section 56.36 of the Civil Code.

(c) The fine for defaulting on a United States Department of Health and Human Services education loan shall not exceed \$2,500.

(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148, 685, 4067 and 4127.4, Business and Professions Code; and Section 56.36, Civil Code.

1775.2. Factors Considered.

In assessing the amount of an administrative fine, except violations of the Confidentiality of Medical Information Act and when assessing a fine pursuant to Business and Professions Code section 685, the following factors shall be considered:

- (a) The gravity of the violation.
- (b) The good or bad faith of the cited person or entity.
- (c) The history of previous violations.
- (d) Evidence that the violation was or was not willful.
- (e) The extent to which the cited person or entity has cooperated with the board's investigation.
- (f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- (g) Other matters as may be appropriate.
- (h) The number of violations found in the investigation.

Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148 and 685, Business and Professions Code; and Section 56.36, Civil Code.

1775.3. Compliance with Orders of Abatement.

(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation

because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request, from the board, an extension of time in which to complete the correction. Such a request shall be in writing and shall be made within the time set forth for abatement.

(b) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. An order of abatement shall either be personally served or mailed by certified mail. Failure to comply with an order of abatement shall constitute a ground for revocation or suspension of the license, permit, or registration.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code.
Reference: Sections 125.9 and 148, Business and Professions Code.

1775.4. Contested Citations.

(a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)

(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendar days of receiving the request.

(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.

(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Article 10. Wholesalers

1780. Minimum Standards for Wholesalers.

The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:

- (a) A wholesaler shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision).
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- (1) All facilities shall be equipped with an alarm system to detect entry after hours.
- (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (3) The outside perimeter of the wholesaler premises shall be well-lighted.
- (d) All materials must be examined upon receipt or before shipment.
- (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
- (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
- (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
- (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
- (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves

that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.

In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.

(a) Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.

(b) Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

(c) Dangerous drugs, legend drugs or extra label use drugs returned to a veterinary food-animal drug retailer from a client shall be treated as damaged or outdated prescription drugs and stored in the quarantine area specified in section 1780(e)(1). Returned drugs may not be returned to stock, or dispensed, distributed or resold.

(d) A pharmacist or person issued a permit under Business and Professions Code section 4053 (hereafter called a vet retailer designated representative)

may dispense drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian. Only a pharmacist or the vet retailer designated representative may receive an oral order for a veterinary food-animal drug from the veterinarian. A written copy of the oral prescription shall be sent or electronically transmitted to the prescribing veterinarian within 72 hours.

(e) When a vet retailer designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.

(f) Whenever a vet retailer designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.

(g) Refilling a veterinarian's prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

(h) Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

- (1) Active ingredients or the generic names(s) of the drug
 - (2) Manufacturer of the drug
 - (3) Strength of the drug dispensed
 - (4) Quantity of the drug dispensed
 - (5) Name of the client
 - (6) Species of food-producing animals for which the drug is prescribed
 - (7) Condition for which the drug is prescribed
 - (8) Directions for use
 - (9) Withdrawal time
 - (10) Cautionary statements, if any
 - (11) Name of the veterinarian prescriber
 - (12) Date dispensed
 - (13) Name and address of the veterinary food-animal drug retailer
 - (14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)
 - (15) Manufacturer's expiration date
- (i) A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer designated representative who is responsible for the

distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

(j) If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers). If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

(k) Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

(l) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

(m) Training of Vet Retailer Designated representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer designated representative

who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Authority cited: Sections 4005 and 4197, Business and Professions Code.
Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

1781. Exemption Certificate.

A registered pharmacist, or an designated representative certified in accordance with Section 4053 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

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

1782. Reporting Sales of Drugs Subject to Abuse.

All manufacturers and wholesalers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

1783. Manufacturer or Wholesaler Furnishing Drugs and Devices.

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this

method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer or wholesaler shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer or wholesaler to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer or wholesaler shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

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

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 (Rev. 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 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.

Article 10.1 Home Dialysis Drugs and Devices

1787. Authorization to Distribute Dialysis Drugs and Devices.

(a) Only the following dangerous drugs and devices may be distributed directly to home dialysis patients in case or full shelf package lots:

(1) Dialysate

(2) Heparin 1000u/cc

(3) Sterile Sodium Chloride 0.9% for injection

(4) Needles

(5) Syringes

(6) Dialyzers, delivery systems and their accessory equipment necessary for chronic hemodialysis.

(b) The drugs and devices specified in 1787(a) may be distributed on the basis of a written or oral order received from a licensed prescriber. The prescriber or his or her authorized employee may transmit oral orders directly to a pharmacist or designated representative.

(c) Orders are refillable during a six-month interval as ordered by the prescriber. Records of such refills shall be retained by the supplier for three years.

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

1790. Assembling and Packaging.

A record of shipment or expanded invoice shall be included in the patient's shipment, and shall include the name(s) of the drugs or devices, quantities, manufacturer's name and lot number, date of shipment, and the name of the pharmacist or designated representative who supervised and was responsible for the distribution. Copies of the record shall also be distributed to the prescribing physician and retained by the supplier for three years.

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

1791. Labeling.

In addition to the manufacturer's label, each case or full shelf package furnished to a home hemodialysis patient shall have affixed in a conspicuous place the name of that patient. In addition the shipment must include the following information: the patient's name and address, the name, strength, dosage size and quantity of the dangerous drugs or devices contained therein, the name of the prescriber, the name and address of the supplier, the date of assembly, and appropriate directions for use.

Authority cited: Sections 4005 and 4059, Business and Professions Code.

Reference: Sections 4059, 4081 and 4332, Business and Professions Code.

1792. Receipt for Shipment.

Upon delivery of such drugs and devices, the supplier or his or her agent shall obtain the signature of the patient or his or her agent on the invoice with notations of any discrepancies, corrections or damage.

Authority cited: Sections 4005 and 4059, Business and Professions Code.

Reference: Sections 4059, 4081 and 4332, Business and Professions Code.

Article 11. Ancillary Personnel

1793. Definitions.

"Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a pharmacy, but who does not perform duties restricted to a pharmacist under section 1793.1.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.1. Duties of a Pharmacist.

Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(g) Perform all functions which require professional judgment.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.2. Duties of a Pharmacy Technician.

“Nondiscretionary tasks” as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.3. Other Non-Licensed Pharmacy Personnel.

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

(c) A pharmacist who, exercising his or her professional judgment pursuant to subdivision (b), refuses to supervise the number of non-licensed personnel scheduled by the pharmacy, shall notify the pharmacist-in-charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the non-licensed personnel that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule.

(d) No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Sections 4005 and 4007, Business and Professions Code.
Reference: Sections 4005 and 4007, Business and Professions Code.

1793.5. Pharmacy Technician Application.

Operative 1/1/2016

The "Pharmacy Technician Application" (Form 17A-5 (Rev. 10/15)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and

knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the

Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist. Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052.1 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

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

HEALTH & SAFETY CODE

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HEALTH & SAFETY CODE

Division 2. Licensing Provisions

1261.5. Emergency Supplies; Doses Stored in Emergency Supplies Container

(a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4119 of the Business and Professions Code, shall be limited to 48. The State Department of Public Health may limit the number of doses of each drug available to not more than 16 doses of any separate drug dosage form in each emergency supply.

(b) Not more than four of the 48 oral form or suppository form drugs secured for storage in the emergency supplies container shall be psychotherapeutic drugs, except that the department may grant a program flexibility request to the facility to increase the number of psychotherapeutic drugs in the emergency supplies container to not more than 10 if the facility can demonstrate the necessity for an increased number of drugs based on the needs of the patient population at the facility. In addition, the four oral form or suppository form psychotherapeutic drug limit shall not apply to a special treatment program service unit distinct part, as defined in Section 1276.9. The department shall limit the number of doses of psychotherapeutic drugs available to not more than four doses in each emergency supply. Nothing in this section shall alter or diminish informed consent requirements, including, but not limited to, the requirements of Section 1418.9.

(c) Any limitations established pursuant to subdivisions (a) and (b) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs.

1261.6 Automated Drug Delivery Systems

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

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

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

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

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

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

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

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

DIVISION 10. UNIFORM CONTROLLED SUBSTANCE ACT

CHAPTER 1. GENERAL PROVISIONS AND DEFINITIONS

11000. Designation

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

11001. Definitions Govern Construction

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

11002. Administer Defined

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his immediate needs or to the body of a research subject by any of the following:

- (a) A practitioner or, in his presence, by his authorized agent.
- (b) The patient or research subject at the direction and in the presence of the practitioner.

11003. Agent Defined

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

11004. Attorney General Defined

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

11005. Board of Pharmacy Defined

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

11006.5. Concentrated Cannabis Defined

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

11007. Controlled Substance Defined

"Controlled substance," unless otherwise specified, means a drug, substance, or immediate precursor which is listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058.

11008. Customs Broker Defined

"Customs broker" means a person in this state who is authorized to act as a broker for any of the following:

- (a) A person in this state who is licensed to sell, distribute, or otherwise possess any controlled substance.
- (b) A person in any other state who ships any controlled substance into this state.
- (c) A person in this state or any other state who ships or transfers any controlled substance through this state.

11009. Deliver or Delivery Defined

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

11010. Dispense Defined

"Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

11011. Dispenser Defined

"Dispenser" means a practitioner who dispenses.

11012. Distribute Defined

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

11013. Distributor Defined

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

11014. Drug Defined

"Drug" means (a) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (c) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (d) substances intended for use as a component of any article specified in subdivision (a), (b), or (c) of this section. It does not include devices or their components, parts, or accessories.

11014.5. Drug Paraphernalia Defined

(a) "Drug paraphernalia" means all equipment, products and materials of any kind which are designed for use or marketed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this division. It includes, but is not limited to:

(1) Kits designed for use or marketed for use in planting, propagating, cultivating, growing, or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.

(2) Kits designed for use or marketed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

- (3) Isomerization devices designed for use or marketed for use in increasing the potency of any species of plant which is a controlled substance.
- (4) Testing equipment designed for use or marketed for use in identifying, or in analyzing the strength, effectiveness, or purity of controlled substances.
- (5) Scales and balances designed for use or marketed for use in weighing or measuring controlled substances.
- (6) Containers and other objects designed for use or marketed for use in storing or concealing controlled substances.
- (7) Hypodermic syringes, needles, and other objects designed for use or marketed for use in parenterally injecting controlled substances into the human body.
- (8) Objects designed for use or marketed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:
- (A) Carburetion tubes and devices.
 - (B) Smoking and carburetion masks.
 - (C) Roach clips, meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand.
 - (D) Miniature cocaine spoons, and cocaine vials.
 - (E) Chamber pipes.
 - (F) Carburetor pipes.
 - (G) Electric pipes.
 - (H) Air-driven pipes.
 - (I) Chillums.
 - (J) Bongs.
 - (K) Ice pipes or chillers.
- (b) For the purposes of this section, the phrase "marketed for use" means advertising, distributing, offering for sale, displaying for sale, or selling in a manner which promotes the use of equipment, products, or materials with controlled substances.
- (c) In determining whether an object is drug paraphernalia, a court or other authority may consider, in addition to all other logically relevant factors, the following:
- (1) Statements by an owner or by anyone in control of the object concerning its use.
 - (2) Instructions, oral or written, provided with the object concerning its use for ingesting, inhaling, or otherwise introducing a controlled substance into the human body.
 - (3) Descriptive materials accompanying the object which explain or depict its use.
 - (4) National and local advertising concerning its use.
 - (5) The manner in which the object is displayed for sale.
 - (6) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products.
 - (7) Expert testimony concerning its use.

(d) If any provision of this section or the application thereof to any person or circumstance is held invalid, it is the intent of the Legislature that the invalidity shall not affect other provisions or applications of the section which can be given effect without the invalid provision or application and to this end the provisions of this section are severable.

11015. Federal Bureau Defined

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

11016. Furnish Defined

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

11017. Manufacturer Defined

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

11018. Marijuana Defined

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

(Added by Stats. 1972, Ch. 1407. Superseded on operative date of amendment by Stats. 2013, Ch. 398.)

11018. Marijuana Defined

"Marijuana" means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds of that plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include industrial hemp, as defined in Section 11018.5, except where the plant is cultivated or processed for purposes not expressly allowed for by Division 24 (commencing with Section 81000) of the Food and Agricultural Code.

(Amended by Stats. 2013, Ch. 398, Sec. 5. Effective January 1, 2014. Conditionally operative as prescribed by Sec. 8 of Ch. 398.)

11018.5. Industrial Hemp Defined

"Industrial hemp" means a fiber or oilseed crop, or both, that is limited to nonpsychoactive types of the plant *Cannabis sativa* L. and the seed produced therefrom, having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, and that is cultivated and processed exclusively for the purpose of producing the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the

plant, or any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin or flowering tops extracted therefrom, fiber, oil, or cake, or the sterilized seed, or any component of the seed, of the plant that is incapable of germination.

(Added by Stats. 2013, Ch. 398, Sec. 6. Effective January 1, 2014. Conditionally operative as prescribed by Sec. 8 of Ch. 398.)

11019. Narcotic Drug Defined

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(b) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in subdivision (a), but not including the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(e) Cocaine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(f) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(g) Acetylfentanyl, the thiophene analog thereof, derivatives of either, and any salt, compound, isomer, or preparation of acetylfentanyl or the thiophene analog thereof.

11020. Opiate Defined

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Chapter 2 (commencing with Section 11053) of this division, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

11021. Opium Poppy Defined

"Opium poppy" means the plant of the species *Papaver somniferum* L., except its seeds.

11022. Person Defined

"Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, limited liability company, or association, or any other legal entity.

11023. Pharmacy Defined

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

11024. Physician, Dentist, Podiatrist, Pharmacist, and Veterinarian Defined

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

11025. Poppy Straw Defined

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

11026. Practitioner Defined

"Practitioner" means any of the following:

(a) A physician, dentist, veterinarian, podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, or a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code.

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer, a controlled substance in the course of professional practice or research in this state.

(c) A scientific investigator, or other person licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.

11027. Prescription Defined

(a) "Prescription" means an oral order or electronic transmission prescription for a controlled substance given individually for the person(s) for whom prescribed, directly from the prescriber to the furnisher or indirectly by means of a written order of the prescriber.

(b) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" is any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" is any

prescription order, other than an electronic image transmission prescription, which is electronically transmitted from a licensed prescriber to a pharmacy.

11029. Production Defined

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

11029.5. Security Printer Defined

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

11030. Ultimate User Defined

"Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

11031. Wholesaler Defined

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

11032. References to Narcotics, Restricted Dangerous Drugs, Marijuana as Schedule I, II, III and IV Controlled Substances

Whenever reference is made to the term "narcotics" in any provision of law outside of this division, unless otherwise expressly provided, it shall be construed to mean controlled substances classified in Schedules I and II, as defined in this division. Whenever reference is made to "restricted dangerous drugs" outside of this division, unless otherwise expressly provided, it shall be construed to mean controlled substances classified in Schedules III and IV. Whenever reference is made to the term "marijuana" in any provision of law outside of this division, unless otherwise expressly provided, it shall be construed to mean marijuana as defined in this division.

11033. Isomer Defined

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

CHAPTER 2. STANDARDS AND SCHEDULES

11053. Substances Included by Whatever Name Used

The controlled substances listed or to be listed in the schedules in this chapter are included by whatever official, common, usual, chemical, or trade name designated.

11054. Schedule I Controlled Substances

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

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Acetylmethadol.
- (2) Allylprodine.
- (3) Alphacetylmethadol (except levoalphacetylmethadol, also known as levo-alpha- acetylmethadol, levomethadyl acetate, or LAAM).
- (4) Alphameprodine.
- (5) Alphamethadol.
- (6) Benzethidine.
- (7) Betacetylmethadol.
- (8) Betameprodine.
- (9) Betamethadol.
- (10) Betaprodine.
- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Diampromide.
- (14) Diethylthiambutene.
- (15) Difenoxin.
- (16) Dimenoxadol.
- (17) Dimepheptanol.
- (18) Dimethylthiambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoperidine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacymorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpipanone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.
- (39) Proheptazine.
- (40) Properidine.
- (41) Propiram.
- (42) Racemoramide.

(43) Tilidine.

(44) Trimeperidine.

(45) Any substance which contains any quantity of acetylfentanyl (N-(1-phenethyl-4-piperidiny) acetanilide) or a derivative thereof.

(46) Any substance which contains any quantity of the thiophene analog of acetylfentanyl (N-(1-(2-(2-thienyl)ethyl)-4- piperidiny) acetanilide) or a derivative thereof.

(47) 1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).

(48) 1-(2-Phenethyl)-4-Phenyl-4-Acetyloxypiperidine (PEPAP).

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Drotebanol.

(10) Etorphine (except hydrochloride salt).

(11) Heroin.

(12) Hydromorphanol.

(13) Methyldesorphine.

(14) Methyldihydromorphine.

(15) Morphine methylbromide.

(16) Morphine methylsulfonate.

(17) Morphine-N-Oxide.

(18) Myrophine.

(19) Nicocodeine.

(20) Nicomorphine.

(21) Normorphine.

(22) Pholcodine.

(23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 4-bromo-2,5-dimethoxy-amphetamine--Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine;
4-bromo-2,5-DMA.

- (2) 2,5-dimethoxyamphetamine--Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.
- (3) 4-methoxyamphetamine--Some trade or other names: 4-methoxy-alpha-methylphenethylamine, paramethoxyamphetamine, PMA.
- (4) 5-methoxy-3,4-methylenedioxy-amphetamine.
- (5) 4-methyl-2,5-dimethoxy-amphetamine--Some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP."
- (6) 3,4-methylenedioxy amphetamine.
- (7) 3,4,5-trimethoxy amphetamine.
- (8) Bufotenine--Some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2- dimethylaminoethyl)-5indolol; N,N-dimethylserotonin, 5-hydroxy-N,N-dimethyltryptamine; mappine.
- (9) Diethyltryptamine--Some trade or other names:N,N-Diethyltryptamine; DET.
- (10) Dimethyltryptamine--Some trade or other names: DMT.
- (11) Ibogaine--Some trade or other names: 7-Ethyl-6,6beta, 7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5Hpyrido (1',2':1,2) azepino (5,4-b) indole; Tabernantheiboga.
- (12) Lysergic acid diethylamide.
- (13) Marijuana.
- (14) Mescaline.
- (15) Peyote—Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts (interprets 21 U.S.C. Sec. 812(c), Schedule 1(c)(12)).
- (16) N-ethyl-3-piperidyl benzilate.
- (17) N-methyl-3-piperidyl benzilate.
- (18) Psilocybin.
- (19) Psilocyn.
- (20) Tetrahydrocannabinols. Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following: delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; delta 3,4 cis or trans tetrahydrocannabinol, and its optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).
- (21) Ethylamine analog of phencyclidine--Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE.
- (22) Pyrrolidine analog of phencyclidine--Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCP, PHP.
- (23) Thiophene analog of phencyclidine--Some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine, 2- thienyl analog of phencyclidine, TPCP, TCP.

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

- (1) Mecloqualone.
- (2) Methaqualone.
- (3) Gamma hydroxybutyric acid (also known by other names such as GHB; gamma hydroxy butyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate), including its immediate precursors, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, including, but not limited to, gammabutyrolactone, for which an application has not been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its isomers:

- (1) Cocaine base.
- (2) Fenethylamine, including its salts.
- (3) N-Ethylamphetamine, including its salts.

11055. Schedule II Controlled Substances

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

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

- (A) Raw opium.
- (B) Opium extracts.
- (C) Opium fluid extracts.
- (D) Powdered opium.
- (E) Granulated opium.
- (F) Tincture of opium.
- (G) Codeine.
- (H) Ethylmorphine.
- (I) Hydrocodone.
- (J) Hydromorphone.
- (K) Metopon.
- (L) Morphine.
- (M) Oxycodone.
- (N) Oxymorphone.
- (O) Thebaine.

(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(6) Cocaine, except as specified in Section 11054.

(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(8) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:

(1) Alfentanyl.

(2) Alphaprodine.

(3) Anileridine.

(4) Bezitramide.

(5) Bulk dextropropoxyphene (nondosage forms).

(6) Dihydrocodeine.

(7) Diphenoxylate.

(8) Fentanyl.

(9) Isomethadone.

(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).

(11) Levomethorphan.

(12) Levorphanol.

(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

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

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) Khat, which includes all parts of the plant classified botanically as *Catha Edulis*, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(8) Cathinone (also known as alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone).

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

(1) Amobarbital.

(2) Pentobarbital.

(3) Phencyclidines, including the following:

(A) 1-(1-phenylcyclohexyl) piperidine (PCP).

(B) 1-(1-phenylcyclohexyl) morpholine (PCM).

(C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph. The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted, submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.

(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(A) Phenylacetone. Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

11056. Schedule III Controlled Substances

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

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

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

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

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

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

(A) Amobarbital

(B) Secobarbital

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

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

(A) Amobarbital

(B) Secobarbital

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

- (3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof.
- (4) Chlorhexadol.
- (5) Lysergic acid.
- (6) Lysergic acid amide.
- (7) Methypylon.
- (8) Sulfondiethylmethane.
- (9) Sulfonethylmethane.
- (10) Sulfonmethane.
- (11) Gamma hydroxybutyric acid, and its salts, isomers and salts of isomers, contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).
- (d) Nalorphine.
- (e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
- (1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
- (2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.
- (4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts. Additionally, oral liquid preparations of dihydrocodeinone containing the above specified amounts may not contain as its nonnarcotic ingredients two or more antihistamines in combination with each other.
- (5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.
- (6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt

Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:

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

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

11057. Schedule IV Controlled Substances

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

(b) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

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

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane).

(3) Butorphanol.

(d) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam.

(2) Barbitol.

(3) Chloral betaine.

(4) Chloral hydrate.

(5) Chlordiazepoxide.

(6) Clobazam.

(7) Clonazepam.

(8) Clorazepate.

(9) Diazepam.

(10) Estazolam.

(11) Ethchlorvynol.

(12) Ethinamate.

(13) Flunitrazepam.

(14) Flurazepam.

(15) Halazepam.

(16) Lorazepam.

(17) Mebutamate.

(18) Meprobamate.

(19) Methohexital.

(20) Methylphenobarbital (Mephobarbital).

(21) Midazolam.

(22) Nitrazepam.

(23) Oxazepam.

(24) Paraldehyde.

(25) Petrichoral.

(26) Phenobarbital.

(27) Prazepam.

(28) Quazepam.

(29) Temazepam.

(30) Triazolam.

(31) Zaleplon.

(32) Zolpidem.

(e) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers, whenever the existence of those salts, isomers, and salts of isomers is possible:

(1) Fenfluramine.

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

(1) Diethylpropion.

(2) Mazindol.

(3) Modafinil.

(4) Phentermine.

(5) Pemoline (including organometallic complexes and chelates thereof).

(6) Pipradrol.

(7) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(8) Cathine ((+)-norpseudoephedrine).

(g) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pentazocine, including its salts.

11058. Schedule V Controlled Substances

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

(b) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(c) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) Buprenorphine.

CHAPTER 3. REGULATION AND CONTROL

Article 1. Reporting

11100. Report of Certain Chemical: Chemicals Included; Exclusions; Penalties

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

- (1) Phenyl-2-propanone.
- (2) Methylamine.
- (3) Ethylamine.
- (4) D-lysergic acid.
- (5) Ergotamine tartrate.
- (6) Diethyl malonate.
- (7) Malonic acid.
- (8) Ethyl malonate.
- (9) Barbituric acid.
- (10) Piperidine.
- (11) N-acetylanthranilic acid.
- (12) Pyrrolidine.
- (13) Phenylacetic acid.
- (14) Anthranilic acid.
- (15) Morpholine.
- (16) Ephedrine.
- (17) Pseudoephedrine.
- (18) Norpseudoephedrine.
- (19) Phenylpropanolamine.
- (20) Propionic anhydride.
- (21) Isosafrole.
- (22) Safrole.
- (23) Piperonal.
- (24) Thionyl chloride.
- (25) Benzyl cyanide.
- (26) Ergonovine maleate.
- (27) N-methylephedrine.
- (28) N-ethylephedrine.
- (29) N-methylpseudoephedrine.
- (30) N-ethylpseudoephedrine.
- (31) Chloroephedrine.
- (32) Chloropseudoephedrine.

(33) Hydriodic acid.

(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).

(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).

(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, “proper identification” for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller’s permit identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; driver’s license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to any person or

business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) Any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars (\$5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars (\$100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

(3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per

transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars (\$10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) “Drug store” is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) “General merchandise store” is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) “Grocery store” is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) “Pediatric liquid” means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) “Retail distributor” means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. “Retail distributor” includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

(6) “Sale for personal use” means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). “Sale for personal use” also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

11100.05. Drug Cleanup Fine

(a) In addition to any fine or imprisonment imposed under subdivision (f) of Section 11100 or subdivision (j) of Section 11106 of the Health and Safety Code, the following drug cleanup fine shall be imposed:

(1) Ten thousand dollars (\$10,000) for violations described in paragraph (1) of subdivision (f) of Section 11100.

(2) One hundred thousand dollars (\$100,000) for violations described in paragraph (2) of subdivision (f) of Section 11100.

(3) Ten thousand dollars (\$10,000) for violations described in subdivision (j) of Section 11106.

(b) At least once a month, all fines collected under this section shall be transferred to the State Treasury for deposit in the Clandestine Drug Lab Clean-up Account. The transmission to the State Treasury shall be carried out in the same manner as fines collected for the state by a county.

11100.1. Report of Chemicals Received from Outside State; Penalties

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that obtains from a source outside of this state any substance specified in subdivision (a) of Section 11100 shall submit a report of that transaction to the Department of Justice 21 days in advance of obtaining the substance. However, the Department of Justice may authorize the submission of reports within 72 hours, or within a timeframe and in a manner acceptable to the Department of Justice, after the actual physical obtaining of a specified substance with respect to repeated transactions between a furnisher and an obtainer involving the substances, if the Department of Justice determines that the obtainer has established a record of utilization of the substances for lawful purposes. This section does not apply to any person whose prescribing or dispensing activities are subject to the reporting requirements set forth in Section 11164; any manufacturer or wholesaler who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration of the United States Department of Justice; any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice; or any state-licensed health care facility.

(b) (1) Any person specified in subdivision (a) who does not submit a report as required by that subdivision shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars (\$5,000), or by both that fine and imprisonment.

(2) Any person specified in subdivision (a) who has been previously convicted of a violation of subdivision (a) who subsequently does not submit a report as required by subdivision (a) shall be punished by imprisonment in the state

prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars (\$100,000), or by both that fine and imprisonment.

11101. Reporting Form Contents

The State Department of Justice shall provide a common reporting form for the substances in Section 11100 which contains at least the following information:

- (a) Name of the substance.
- (b) Quantity of the substance sold, transferred, or furnished.
- (c) The date the substance was sold, transferred, or furnished.
- (d) The name and address of the person buying or receiving such substance.
- (e) The name and address of the manufacturer, wholesaler, retailer, or other person selling, transferring, or furnishing such substance.

11102. Adoption of Necessary Regulations

The Department of Justice may adopt all regulations necessary to carry out the provisions of this part.

11103. Report of Theft, Loss, or Shipping Discrepancy

The theft or loss of any substance regulated pursuant to Section 11100 discovered by any permittee or any person regulated by the provisions of this chapter shall be reported in writing to the Department of Justice within three days after the discovery. Any difference between the quantity of any substance regulated pursuant to Section 11100 received and the quantity shipped shall be reported in writing to the Department of Justice within three days of the receipt of actual knowledge of the discrepancy.

Any report made pursuant to this section shall also include the name of the common carrier or person who transports the substance and date of shipment of the substance.

11104. Providing Chemical for Illicit Manufacturing: Evasion of Reporting Requirements; Penalties

(a) Any manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes any of the substances listed in subdivision (a) of Section 11100 with knowledge or the intent that the recipient will use the substance to unlawfully manufacture a controlled substance is guilty of a felony.

(b) Any manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, or any chemical substance specified in Section 11107.1, with knowledge that the recipient will use the goods or chemical substance to unlawfully manufacture a controlled substance, is guilty of a misdemeanor.

(c) Any person who receives or distributes any substance listed in subdivision (a) of Section 11100, or any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, or any chemical substance

specified in Section 11107.1, with the intent of causing the evasion of the recordkeeping or reporting requirements of this article, is guilty of a misdemeanor.

11104.5. Illegal Possession of Certain Glassware or Lab Apparatus

Any person who knowingly or intentionally possesses any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, or any chemical substance specified in paragraph (36) or (37) of subdivision (a) of Section 11100, Section 11107, or Section 11107.1, with the intent to manufacture a controlled substance, is guilty of a misdemeanor.

11105. False Statement in Report

(a) It is unlawful for any person to knowingly make a false statement in connection with any report or record required under this article.

(b) (1) Any person who violates this section shall be punished by imprisonment in the state prison, or by imprisonment in the county jail not exceeding one year, or by a fine not exceeding five thousand dollars (\$5,000), or by both such fine and imprisonment.

(2) Any person who has been previously convicted of violating this section and who subsequently violates this section shall be punished by imprisonment in the state prison for two, three, or four years, or by a fine not exceeding one hundred thousand dollars (\$100,000), or by both such fine and imprisonment.

11106. Permit for Providing Chemicals; Process; Discipline; Renewal and Fees

(a) (1) (A) Any manufacturer, wholesaler, retailer, or any other person or entity in this state that sells, transfers, or otherwise furnishes any substance specified in subdivision (a) of Section 11100 to a person or business entity in this state or any other state or who obtains from a source outside of the state any substance specified in subdivision (a) of Section 11100 shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice. For any substance added to the list set forth in subdivision (a) of Section 11100 on or after January 1, 2002, the Department of Justice may postpone the effective date of the requirement for a permit for a period not to exceed six months from the listing date of the substance.

(B) An intracompany transfer does not require a permit if the transferor is a permittee. Transfers between company partners or between a company and an analytical laboratory do not require a permit if the transferor is a permittee and a report as to the nature and extent of the transfer is made to the Department of Justice pursuant to Section 11100 or 11100.1.

(C) This paragraph shall not apply to any manufacturer, wholesaler, or wholesale distributor who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration of the United States Department of Justice; any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian; any state-licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food-animal

drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(D) This paragraph shall not apply to the sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person or entity for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.

(3) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1).

(b) (1) The department shall provide application forms, which are to be completed under penalty of perjury, in order to obtain information relating to the identity of any applicant applying for a permit, including, but not limited to, the business name of the applicant or the individual name, and if a corporate entity, the names of its board of directors, the business in which the applicant is engaged, the business address of the applicant, a full description of any substance to be sold, transferred, or otherwise furnished or to be obtained, the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100, the training, experience, or education relating to this use, and any additional information requested by the department relating to possible grounds for denial as set forth in this section, or by applicable regulations adopted by the department.

(2) The requirement for the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100 does not require applicants or permittees to reveal their chemical processes that are typically considered trade secrets and proprietary business information.

(c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.

(d) An application may be denied, or a permit may be revoked or suspended, for reasons which include, but are not limited to, the following:

(1) Materially falsifying an application for a permit or an application for the renewal of a permit.

(2) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, is or has been convicted of a misdemeanor or felony relating to any of the substances listed under subdivision (a) of Section 11100, any misdemeanor drug-related offense, or any felony under the laws of this state or the United States.

(3) Failure to maintain effective controls against the diversion of precursors to unauthorized persons or entities.

(4) Failure to comply with this article or any regulations of the department adopted thereunder.

(5) Failure to provide the department, or any duly authorized federal or state official, with access to any place for which a permit has been issued, or for which an application for a permit has been submitted, in the course of conducting a site investigation, inspection, or audit; or failure to promptly produce for the official conducting the site investigation, inspection, or audit any book, record, or document requested by the official.

(6) Failure to provide adequate documentation of a legitimate business purpose involving the applicant's or permittee's use of any substance listed in subdivision (a) of Section 11100.

(7) Commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions, or duties of a permitholder.

(8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.

(e) Notwithstanding any other provision of law, an investigation of an individual applicant's qualifications, or the qualifications of an applicant's owner, manager, agent, representative, or employee who has direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for a permit may include review of his or her summary criminal history information pursuant to Sections 11105 and 13300 of the Penal Code, including, but not limited to, records of convictions, regardless of whether those convictions have been expunged pursuant to Section 1203.4 of the Penal Code, and any arrests pending adjudication.

(f) The department may retain jurisdiction of a canceled or expired permit in order to proceed with any investigation or disciplinary action relating to a permittee.

(g) The department may grant permits on forms prescribed by it, which shall be effective for not more than one year from the date of issuance and which shall not be transferable. Applications and permits shall be uniform throughout the state, on forms prescribed by the department.

(h) Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department.

(i) A permit granted pursuant to this article may be renewed one year from the date of issuance, and annually thereafter, following the timely filing of a complete renewal application with all supporting documents, the payment of a permit renewal fee not to exceed the application processing costs of the department, and a review of the application by the department.

(j) Selling, transferring, or otherwise furnishing or obtaining any substance specified in subdivision (a) of Section 11100 without a permit is a misdemeanor or a felony.

(k) (1) No person under 18 years of age shall be eligible for a permit under this section.

(2) No business for which a permit has been issued shall employ a person under 18 years of age in the capacity of a manager, agent, or representative.

(l) (1) An applicant, or an applicant's employees who have direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for an initial permit shall submit with the application one set of 10-print fingerprints for each individual acting in the capacity of an owner, manager, agent, or representative for the applicant, unless the applicant's employees are exempted from this requirement by the Department of Justice. These exemptions may only be obtained upon the written request of the applicant.

(2) In the event of subsequent changes in ownership, management, or employment, the permittee shall notify the department in writing within 15 calendar days of the changes, and shall submit one set of 10-print fingerprints for each individual not previously fingerprinted under this section.

11106.5. Order Suspending or Imposing Permit Restrictions

(a) The Department of Justice, or an administrative law judge sitting alone as provided in subdivision (h), may upon petition issue an interim order suspending any permittee or imposing permit restrictions. The petition shall include affidavits that demonstrate, to the satisfaction of the department, both of the following:

(1) The permittee has engaged in acts or omissions constituting a violation of this code or has been convicted of a crime substantially related to the permitted activity.

(2) Permitting the permittee to operate, or to continue to operate without restrictions, would endanger the public health, safety, or welfare.

(b) No interim order provided for in this section shall be issued without notice to the permittee, unless it appears from the petition and supporting documents that serious injury would result to the public before the matter could be heard on notice.

(c) Except as provided in subdivision (b), the permittee shall be given at least 15 days' notice of the hearing on the petition for an interim order. The notice shall include documents submitted to the department in support of the petition. If the order was initially issued without notice as provided in subdivision (b), the permittee shall be entitled to a hearing on the petition within 20 days of the

issuance of the interim order without notice. The permittee shall be given notice of the hearing within two days after issuance of the initial interim order, and shall receive all documents in support of the petition. The failure of the department to provide a hearing within 20 days following issuance of the interim order without notice, unless the permittee waives his or her right to the hearing, shall result in the dissolution of the interim order by operation of law.

(d) At the hearing on the petition for an interim order, the permittee may do the following:

(1) Be represented by counsel.

(2) Have a record made of the proceedings, copies of which shall be available to the permittee upon payment of costs computed in accordance with the provisions for transcript costs for judicial review contained in Section 11523 of the Government Code.

(3) Present affidavits and other documentary evidence.

(4) Present oral argument.

(e) The department, or an administrative law judge sitting alone as provided in subdivision (h), shall issue a decision on the petition for interim order within five business days following submission of the matter. The standard of proof required to obtain an interim order pursuant to this section shall be a preponderance of the evidence standard. If the interim order was previously issued without notice, the department shall determine whether the order shall remain in effect, be dissolved, or be modified.

(f) The department shall file an accusation within 15 days of the issuance of an interim order. In the case of an interim order issued without notice, the time shall run from the date of the order issued after the noticed hearing. If the permittee files a notice of defense, the hearing shall be held within 30 days of the agency's receipt of the notice of defense. A decision shall be rendered on the accusation no later than 30 days after submission of the matter. Failure to comply with any of the requirements in this subdivision shall dissolve the interim order by operation of law.

(g) Interim orders shall be subject to judicial review pursuant to Section 1094.5 of the Code of Civil Procedure and shall be heard only in the superior court in and for the County of Sacramento, San Francisco, Los Angeles, or San Diego. The review of an interim order shall be limited to a determination of whether the department abused its discretion in the issuance of the interim order. Abuse of discretion is established if the respondent department has not proceeded in the manner required by law, or if the court determines that the interim order is not supported by substantial evidence in light of the whole record.

(h) The department may, in its sole discretion, delegate the hearing on any petition for an interim order to an administrative law judge in the Office of Administrative Hearings. If the department hears the noticed petition itself, an administrative law judge shall preside at the hearing, rule on the admission and exclusion of evidence, and advise the department on matters of law. The department shall exercise all other powers relating to the conduct of the hearing, but may delegate any or all of them to the administrative law judge. When the petition has been delegated to an administrative law judge, he or she

shall sit alone and exercise all of the powers of the department relating to the conduct of the hearing. A decision issued by an administrative law judge sitting alone shall be final when it is filed with the department. If the administrative law judge issues an interim order without notice, he or she shall preside at the noticed hearing, unless unavailable, in which case another administrative law judge may hear the matter. The decision of the administrative law judge sitting alone on the petition for an interim order is final, subject only to judicial review in accordance with subdivision (g).

(i) (1) Failure to comply with an interim order issued pursuant to subdivision (a) or (b) shall constitute a separate cause for disciplinary action against any permittee, and may be heard at, and as a part of, the noticed hearing provided for in subdivision (f). Allegations of noncompliance with the interim order may be filed at any time prior to the rendering of a decision on the accusation.

Violation of the interim order is established upon proof that the permittee was on notice of the interim order and its terms, and that the order was in effect at the time of the violation. The finding of a violation of an interim order made at the hearing on the accusation shall be reviewed as a part of any review of a final decision of the department.

(2) If the interim order issued by the department provides for anything less than a complete suspension of the permittee and the permittee violates the interim order prior to the hearing on the accusation provided for in subdivision (f), the department may, upon notice to the permittee and proof of violation, modify or expand the interim order.

(j) A plea or verdict of guilty or a conviction after a plea of nolo contendere is deemed to be a conviction within the meaning of this section. A certified record of the conviction shall be conclusive evidence of the fact that the conviction occurred. The department may take action under this section notwithstanding the fact that an appeal of the conviction may be taken.

(k) The interim orders provided for by this section shall be in addition to, and not a limitation on, the authority to seek injunctive relief provided in any other provision of law.

11106.7. System for DOJ Citations to Permittees; Order of Abatement or Order to Pay Fine; System Requirements

(a) The Department of Justice may establish, by regulation, a system for the issuance to a permittee of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the Department of Justice, if the permittee is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(b) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars (\$2,500) for each violation. In assessing a

fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the permittee, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the permittee that if the permittee desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the department within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the permittee may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied and the order of abatement. However, the permittee does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a permittee to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action being taken by the department. If a citation is not contested and a fine is not paid, the full amount of the assessed fine shall be added to the renewal of the permit. A permit shall not be renewed without payment of the renewal fee and fine.

(c) The system may contain the following provisions:

(1) A citation may be issued without the assessment of an administrative fine.

(2) Assessment of administrative fines may be limited to only particular violations of the law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the General Fund.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a permit if grounds for that suspension or revocation exist.

11107. Sale of Laboratory Items: Required Procedures and Records; Penalties for Violation

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells to any person or entity in this state or any other state, any laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, where the value of the goods sold in the transaction exceeds one hundred dollars (\$100) shall do the following:

(1) Notwithstanding any other law, in any face-to-face or will-call sale, the seller shall prepare a bill of sale which identifies the date of sale, cost of product, method of payment, specific items and quantities purchased, and the proper purchaser identification information, all of which shall be entered onto the bill of sale or a legible copy of the bill of sale, and shall also affix on the bill of sale his or her signature as witness to the purchase and identification of the purchaser.

(A) For the purposes of this section, “proper purchaser identification” includes a valid motor vehicle operator’s license or other official and valid state-issued identification of the purchaser that contains a photograph of the purchaser, and includes the residential or mailing address of the purchaser, other than a post office box number, the motor vehicle license number of the motor vehicle used by the purchaser at the time of purchase, a description of how the substance is to be used, and the signature of the purchaser.

(B) The seller shall retain the original bill of sale containing the purchaser identification information for five years in a readily presentable manner, and present the bill of sale containing the purchaser identification information upon demand by any law enforcement officer or authorized representative of the Attorney General. Copies of these bills of sale obtained by representatives of the Attorney General shall be maintained by the Department of Justice for a period of not less than five years.

(2) (A) Notwithstanding any other law, in all sales other than face-to-face or will-call sales the seller shall maintain for a period of five years the following sales information: the name and address of the purchaser, date of sale, product description, cost of product, method of payment, method of delivery, delivery address, and valid identifying information.

(B) For the purposes of this paragraph, “valid identifying information” includes two or more of the following: federal tax identification number; resale tax identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; motor vehicle operator’s license; or other identification issued by a state.

(C) The seller shall, upon the request of any law enforcement officer or any authorized representative of the Attorney General, produce a report or record of sale containing the information in a readily presentable manner.

(D) If a common carrier is used, the seller shall maintain a manifest regarding the delivery in a readily presentable manner and for a period of five years.

(b) This section shall not apply to any wholesaler who is licensed by the California State Board of Pharmacy and registered with the federal Drug Enforcement Administration of the United States Department of Justice and who sells laboratory glassware or apparatus, any chemical reagent or solvent, or any combination thereof, to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian.

(c) A violation of this section is a misdemeanor.

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

(1) "Laboratory glassware" includes, but is not limited to, condensers, flasks, separatory funnels, and beakers.

(2) "Apparatus" includes, but is not limited to, heating mantles, ring stands, and rheostats.

(3) "Chemical reagent" means a chemical that reacts chemically with one or more precursors, but does not become part of the finished product.

(4) "Chemical solvent" means a chemical that does not react chemically with a precursor or reagent and does not become part of the finished product. A "chemical solvent" helps other chemicals mix, cools chemical reactions, and cleans the finished product.

11107.1. Requirements When Selling Specified Chemicals; Violation as Misdemeanor

(a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells to any person or entity in this state or any other state any quantity of sodium cyanide, potassium cyanide, cyclohexanone, bromobenzene, magnesium turnings, mercuric chloride, sodium metal, lead acetate, palladium black, hydrogen chloride gas, trichlorofluoromethane (fluorotrichloromethane), dichlorodifluoromethane, 1,1,2-trichloro-1,2,2-trifluoroethane (trichlorotrifluoroethane), sodium acetate, or acetic anhydride shall do the following:

(1) (A) Notwithstanding any other provision of law, in any face-to-face or will-call sale, the seller shall prepare a bill of sale which identifies the date of sale, cost of sale, method of payment, the specific items and quantities purchased and the proper purchaser identification information, all of which shall be entered onto the bill of sale or a legible copy of the bill of sale, and shall also affix on the bill of sale his or her signature as witness to the purchase and identification of the purchaser.

(B) For the purposes of this paragraph, "proper purchaser identification" includes a valid driver's license or other official and valid state-issued identification of the purchaser that contains a photograph of the purchaser, and includes the residential or mailing address of the purchaser, other than a post office box number, the motor vehicle license number of the motor vehicle used by the purchaser at the time of purchase, a description of how the substance is to be used, the Environmental Protection Agency certification number or resale tax identification number assigned to the individual or business entity for which

the individual is purchasing any chlorofluorocarbon product, and the signature of the purchaser.

(C) The seller shall retain the original bill of sale containing the purchaser identification information for five years in a readily presentable manner, and present the bill of sale containing the purchaser identification information upon demand by any law enforcement officer or authorized representative of the Attorney General. Copies of these bills of sale obtained by representatives of the Attorney General shall be maintained by the Department of Justice for a period of not less than five years.

(2) (A) Notwithstanding any other law, in all sales other than face-to-face or will-call sales the seller shall maintain for a period of five years the following sales information: the name and address of the purchaser, date of sale, product description, cost of product, method of payment, method of delivery, delivery address, and valid identifying information.

(B) For the purposes of this paragraph, “valid identifying information” includes two or more of the following: federal tax identification number; resale tax identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; driver’s license; or other identification issued by a state.

(C) The seller shall, upon the request of any law enforcement officer or any authorized representative of the Attorney General, produce a report or record of sale containing the information in a readily presentable manner.

(D) If a common carrier is used, the seller shall maintain a manifest regarding the delivery in a readily presentable manner for a period of five years.

(b) Any manufacturer, wholesaler, retailer, or other person or entity in this state that purchases any item listed in subdivision (a) of Section 11107.1 shall do the following:

(1) Provide on the record of purchase information on the source of the items purchased, the date of purchase, a description of the specific items, the quantities of each item purchased, and the cost of the items purchased.

(2) Retain the record of purchase for three years in a readily presentable manner and present the record of purchase upon demand to any law enforcement officer or authorized representative of the Attorney General.

(c) (1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars (\$100,000), or both the fine and imprisonment.

11110. Sale of Dextromethorphan Prohibited to Those Under 18 Years of Age without Prescription

(a) It shall be an infraction, punishable by a fine not exceeding two hundred fifty dollars (\$250), for any person, corporation, or retail distributor to willfully and knowingly supply, deliver, or give possession of a drug, material, compound, mixture, preparation, or substance containing any quantity of

dextromethorphan (the dextrorotatory isomer of 3-methoxy-N-methylmorphinan, including its salts, but not including its racemic or levorotatory forms) to a person under 18 years of age in an over-the-counter sale without a prescription.

(b) It shall be prima facie evidence of a violation of this section if the person, corporation, or retail distributor making the sale does not require and obtain bona fide evidence of majority and identity from the purchaser, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be 25 years of age or older.

(c) Proof that a person, corporation, or retail distributor, or his or her agent or employee, demanded, was shown, and acted in reasonable reliance upon, bona fide evidence of majority and identity shall be a defense to any criminal prosecution under this section. As used in this section, "bona fide evidence of majority and identity" means a document issued by a federal, state, county, or municipal government, or subdivision or agency thereof, including, but not limited to, a motor vehicle operator's license, California state identification card, identification card issued to a member of the Armed Forces, or other form of identification that bears the name, date of birth, description, and picture of the person.

(d) (1) Notwithstanding any other provision of this section, a retail clerk who fails to require and obtain proof of age from the purchaser shall not be guilty of an infraction pursuant to subdivision (a) or subject to any civil penalties.

(2) This subdivision shall not apply to a retail clerk who is a willful participant in an ongoing criminal conspiracy to violate this section.

11111. Use of Cash Register with Age-Verification Feature for OTC Sale of Dextromethorphan

A person, corporation, or retail distributor that sells or makes available products containing dextromethorphan, as defined in subdivision (a) of Section 11110, in an over-the-counter sale without a prescription shall, if feasible, use a cash register that is equipped with an age-verification feature to monitor age-restricted items. The cash register shall be programmed to direct the retail clerk making the sale to request bona fide evidence of majority and identity, as described in subdivision (c) of Section 11110, before a product containing dextromethorphan may be purchased.

CHAPTER 4. PRESCRIPTIONS

Article 1 – Requirements of Prescriptions

11150. Persons Authorized to Write or Issue a Prescription

No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the

Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

11150.6. Methaqualone as Schedule I Controlled Substance

Notwithstanding Section 11150.5 or subdivision (a) of Section 11054, methaqualone, its salts, isomers, and salts of its isomers shall be deemed to be classified in Schedule I for the purposes of this chapter.

11151. Limitations on Filling Prescriptions From Medical Students

A prescription written by an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business and Professions Code, shall be filled only at a pharmacy maintained in the hospital which employs such unlicensed person.

11152. Nonconforming Prescriptions Prohibited

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

11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

(b) Any person who knowingly violates this section shall be punished by imprisonment in the state prison or in the county jail not exceeding one year, or

by a fine not exceeding twenty thousand dollars (\$20,000), or by both a fine and imprisonment.

(c) No provision of the amendments to this section enacted during the second year of the 1981-82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

11153.5. Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes.

(b) Anyone who violates this section knowing, or having a conscious disregard for the fact, that the controlled substances are for other than a legitimate medical purpose shall be punishable by imprisonment in the state prison, or in the county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both a fine and imprisonment.

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

11154. Prescription, etc. Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.

(a) Except in the regular practice of his or her profession, no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person or animal which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance, except as provided in this division.

(b) No person shall knowingly solicit, direct, induce, aid, or encourage a practitioner authorized to write a prescription to unlawfully prescribe, administer, dispense, or furnish a controlled substance.

11155. Prohibition on Physician Prescribing, etc. Where Controlled Substance Privileges Surrendered

Any physician, who by court order or order of any state or governmental agency, or who voluntarily surrenders his controlled substance privileges, shall not possess, administer, dispense, or prescribe a controlled substance unless and until such privileges have been restored, and he has obtained current registration from the appropriate federal agency as provided by law.

11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized

(a) Except as provided in Section 2241 of the Business and Professions Code, no person shall prescribe for, or administer, or dispense a controlled substance to, an addict, or to any person representing himself or herself as such, except as permitted by this division.

(b) (1) For purposes of this section, "addict" means a person whose actions are characterized by craving in combination with one or more of the following:

- (A) Impaired control over drug use.
- (B) Compulsive use.
- (C) Continued use despite harm.

(2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section.

11157. No False or Fictitious Prescriptions

No person shall issue a prescription that is false or fictitious in any respect.

11158. Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration

(a) Except as provided in Section 11159 or in subdivision (b) of this section, no controlled substance classified in Schedule II shall be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance classified in Schedule III, IV, or V may be dispensed without a prescription meeting the requirements of this chapter.

(b) A practitioner specified in Section 11150 may dispense directly to an ultimate user a controlled substance classified in Schedule II in an amount not to exceed a 72-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only where the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours. Practitioners dispensing drugs pursuant to this subdivision shall meet the requirements of subdivision (f) of Section 11164.

(c) Except as otherwise prohibited or limited by law, a practitioner specified in Section 11150, may administer controlled substances in the regular practice of his or her profession.

11159. Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years

An order for controlled substances for use by a patient in a county or licensed hospital shall be exempt from all requirements of this article, but shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually administered. The record of such orders shall be maintained as a hospital record for a minimum of seven years.

11159.1. Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years

An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code. Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

11159.2. Exception to Controlled Substance Prescription Requirement; Terminally Ill Patient

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

- (1) Contain the information specified in subdivision (a) of Section 11164.
- (2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

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

11161. Controlled Substance Prescription Blanks; Issuance by Department; Unlawful Possession; Restriction in Criminal Proceeding

(a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all controlled substance prescription forms in the practitioner's possession at a time set in the order and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription forms in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using controlled substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

11161.5. Prescription Forms for Controlled Substance Prescriptions; Requirements

(a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).

(5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (l) of Section 11105 of the Penal Code. Requests for federal level criminal

offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.

(d) The department may deny a security printer application on any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

(i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or e-mail within 24 hours of the theft or loss.

(l) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(m) The following violations by security printers shall be punishable pursuant to subdivision (n):

(1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.

(2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.

(3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.

(n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):

(1) For a first violation, a fine not to exceed one thousand dollars (\$1,000).

(2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars (\$2,500) for each violation.

(3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.

11161.7. Prescriber Authority to Prescribe Restricted; Information to Board; Board Notification to Security Printers

(a) When a prescriber's authority to prescribe controlled substances is restricted by civil, criminal, or administrative action, or by an order of the court issued pursuant to Section 11161, the law enforcement agency or licensing board that sought the restrictions shall provide the name, category of licensure, license number, and the nature of the restrictions imposed on the prescriber to security printers, the Department of Justice, and the Board of Pharmacy.

(b) The Board of Pharmacy shall make available the information required by subdivision (a) to pharmacies and security printers to prevent the dispensing of controlled substance prescriptions issued by the prescriber and the ordering of additional controlled substance prescription forms by the restricted prescriber.

11162.1. Prescription Forms for Controlled Substances; Requirements

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

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

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

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

(d) This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.

11162.5. Counterfeiting or Possession of Counterfeit Controlled Substance Prescription Blank; Penalty

(a) Every person who counterfeits a prescription blank purporting to be an official prescription blank prepared and issued pursuant to Section 11161.5, or knowingly possesses more than three counterfeited prescription blanks, shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code or by imprisonment in a county jail for not more than one year.

(b) Every person who knowingly possesses three or fewer counterfeited prescription blanks purporting to be official prescription blanks prepared and issued pursuant to Section 11161.5, shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, or by a fine not exceeding one thousand dollars (\$1,000), or by both that fine and imprisonment.

11162.6. Controlled Substance Prescription Form; Counterfeiting, Possession of, Attempt to Obtain or Obtain Under False Pretenses; Penalty

(a) Every person who counterfeits a controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail for not more than one year, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.

(b) Every person who knowingly possesses a counterfeited controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.

(c) Every person who attempts to obtain or obtains a controlled substance prescription form under false pretenses shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.

(d) Every person who fraudulently produces controlled substance prescription forms shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.

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

11164. Prescribing, Filling, Compounding or Dispensing Prescription for Controlled Substance; Requirements

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

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

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

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

11164.1. Controlled Substance Prescription Issued in Another State for Delivery to Patient in Another State; Dispensing by California Pharmacy

- (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.
- (2) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.
- (b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

11164.5. Electronic Prescriptions or Orders to Pharmacies and Hospitals

- (a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.
- (b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.
- (c) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the

previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

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

11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Department of Justice

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

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

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or

more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

11165.1. History of Controlled Substances Dispensed to an Individual/PDMP

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

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

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

11165.2. CURES Violation: Citations; Request for Hearing; Fines

(a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its users.

(b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(c) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars (\$2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not contested and a fine is not paid, the subscriber account will be terminated:

(A) A citation may be issued without the assessment of an administrative fine.

(B) Assessment of administrative fines may be limited to only particular violations of law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued

pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

11165.3. Report Theft/Loss of Security Forms

The theft or loss of prescription forms shall be reported immediately by the security printer or affected prescriber to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. This notification may be done in writing utilizing the approved Department of Justice form or may be reported by the authorized subscriber through the CURES Prescription Drug Monitoring Program.

11165.4. CURES; Prescribers' Duty Required to Consult

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient, he or she shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before he or she prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of

the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason he or she did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because

of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within his or her control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

11165.5. CURES Funding; Definitions

(a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

(b) For purposes of this section, the following definitions apply:

(1) “Controlled substance” means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(2) “Health care service plan” means an entity 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).

(3) “Insurer” means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers’ compensation insurance, as defined in Section 109 of the Insurance Code.

(4) “Qualified manufacturer” means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

11166. Time Limit for Filling a Controlled Substance Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited

No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

11167. Emergency Dispensing of Controlled Substance; Circumstances and Requirements

Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the

seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

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

11167.5. Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements

(a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall, prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

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

11170. Prohibition on Prescribing, etc. Controlled Substance for Self

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

11171. Prescribing, etc. Controlled Substance Only as Authorized

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

11172. Antedating or Postdating Prescription Prohibited

No person shall antedate or postdate a prescription.

11173. Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label

(a) No person shall obtain or attempt to obtain controlled substances, or procure or attempt to procure the administration of or prescription for controlled substances, (1) by fraud, deceit, misrepresentation, or subterfuge; or (2) by the concealment of a material fact.

(b) No person shall make a false statement in any prescription, order, report, or record, required by this division.

(c) No person shall, for the purpose of obtaining controlled substances, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, registered nurse, physician's assistant, or other authorized person.

(d) No person shall affix any false or forged label to a package or receptacle containing controlled substances.

11174. Prohibition on Providing False Name or Address in Connection with Prescription, etc.

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

11175. Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription

No person shall obtain or possess a prescription that does not comply with this division, nor shall any person obtain a controlled substance by means of a prescription which does not comply with this division or possess a controlled substance obtained by such a prescription.

11179. Retention of Controlled Substance Prescription

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

11180. Prohibition of Controlled Substance Obtained or Possessed by Nonconforming Prescription

No person shall obtain or possess a controlled substance obtained by a prescription that does not comply with this division.

Article 2. Prescriber's Record

11190. Prescriber's Record for Schedule II, III or IV Controlled Substance; Prescription Requirements

(a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

(D) Quantity of the controlled substance dispensed.

(E) ICD-9 (diagnosis code), if available.

(F) Number of refills ordered.

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

(H) Date of origin of the prescription.

(2) (A) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly basis in a format set by the Department of Justice pursuant to regulation.

(B) The reporting requirement in this section shall not apply to the direct administration of a controlled substance to the body of an ultimate user.

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

(e) The reporting requirement in this section for Schedule IV controlled substances shall not apply to any of the following:

(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.

(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the information required by this section for a Schedule II or Schedule III controlled substance, in a format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all of the following:

(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.

(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

11191. Retention Period; Violation

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

11192. Prima Facie Evidence of Violation of Section 11190

In a prosecution for a violation of Section 11190, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by a defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of a violation of the section.

Article 3. Copies of Prescriptions

11195. Providing Receipt for Prescription Removed by Peace Officer, Board Inspector, etc.

Whenever the pharmacist's copy of a controlled substance prescription is removed by a peace officer, agent of the Attorney General, or inspector of the Board of Pharmacy, or investigator of the Division of Investigation of the Department of Consumer Affairs for the purpose of investigation or as evidence, the officer or inspector or investigator shall give to the pharmacist a receipt in lieu thereof.

Article 4. Refilling Prescriptions

11200. Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Prohibited

(a) No person shall dispense or refill a controlled substance prescription more than six months after the date thereof.

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

(c) No prescription for a Schedule II substance may be refilled.

11201. Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements

A prescription for a controlled substance, except those appearing in schedule II, may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall refill only a reasonable amount sufficient to maintain the patient until the prescriber can be contacted. The pharmacist shall note on the reverse side of the prescription the date and quantity of the refill and that the prescriber was not available and the basis for his judgment to refill the prescription without the prescriber's authorization. The pharmacist shall inform the patient that the prescription was refilled without the prescriber's authorization, indicating that the prescriber was not available and that, in the pharmacist's professional judgment, failure to provide the drug might result in an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall inform the prescriber within a reasonable period of time. Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber.

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

Article 5. Pharmacists' Records

11205. Maintenance and Retention of Records in Separate File

The owner of a pharmacy or any person who purchases a controlled substance upon federal order forms as required pursuant to the provisions of the Federal "Comprehensive Drug Abuse Prevention and Control Act of 1970," (P.L. 91-513, 84 Stat. 1236), relating to the importation, exportation, manufacture, production, compounding, distribution, dispensing, and control of controlled substances, and who sells controlled substances obtained upon such federal order forms in response to prescriptions shall maintain and file such prescriptions in a separate file apart from noncontrolled substances prescriptions. Such files shall be preserved for a period of three years.

11206. Required Information on Prescription

Filed prescriptions shall constitute a transaction record that, together with information that is readily retrievable in the pharmacy pursuant to Section 11164 shall show or include the following:

- (a) The name(s) and address of the patient(s).
- (b) The date.
- (c) The character, including the name and strength, quantity, and directions for use of the controlled substance involved.
- (d) The name, address, telephone number, category of professional licensure, and the federal controlled substance registration number of the prescriber.

11207. Only Pharmacist or Intern Authorized to Fill Prescription

(a) No person other than a pharmacist as defined in Section 4036 of the Business and Professions Code or an intern pharmacist, as defined in Section 4030 of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.

(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

11208. Prima Facie Evidence of Violation of Controlled Substance Act

In a prosecution under this division, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by the defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of guilt.

11209. Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation

(a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

(b) The delivery receipt and any record of discrepancy shall be maintained by the wholesaler or manufacturer for a period of three years.

(c) A violation of this section is a misdemeanor.

(d) Nothing in this section shall require a common carrier to label a package containing controlled substances in a manner contrary to federal law or regulation.

CHAPTER 5. USE OF CONTROLLED SUBSTANCES**Article 1. Lawful Medical Use Other Than Treatment of Addicts****11210. Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed**

A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or

within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

The physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment.

The physician, surgeon, dentist, veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

11211. Purchases of Controlled Substances by Hospital Without a Pharmacist for Emergencies; Conditions on Providing to Patients

In order to provide a supply of controlled substances as may be necessary to handle emergency cases, any hospital which does not employ a resident pharmacist and which is under the supervision of a licensed physician, may

purchase controlled substances on federal order forms for such institution, under the name of such hospital, such supply to be made available to a registered nurse for administration to patients in emergency cases, upon direction of a licensed physician.

11212. Obtaining and Using Controlled Substance for Research, Instruction, or Analysis; Conditions

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes those substances classified in paragraphs (45) and (46) of subdivision (b) of Section 11054 of the Health and Safety Code, upon registration with and approval by the California Department of Justice for use of those substances in bona fide research, instruction, or analysis.

That research, instruction, or analysis shall be carried on only under the auspices of the individual identified by the registrant as responsible for the research. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

The Department of Justice may withdraw approval of the use of such substances at any time. The department may obtain and inspect at any time the records required to be maintained by this section.

11213. Research Approval by Research Advisory Panel

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Article 2. Treatment of Addicts for Addiction

11215. Administration of Narcotics By or Under Direction of Physician, etc.; Who Physician May Direct to Administer

(a) Except as provided in subdivision (b), any narcotic controlled substance employed in treating an addict for addiction shall be administered by:

- (1) A physician and surgeon.
- (2) A registered nurse acting under the instruction of a physician and surgeon.
- (3) A physician assistant licensed pursuant to Chapter 7.7 (commencing with Section 3500) of Division 2 of the Business and Professions Code acting under the patient-specific authority of his or her physician and surgeon supervisor approved pursuant to Section 3515 of the Business and Professions Code.

(b) When acting under the direction of a physician and surgeon, the following persons may administer a narcotic controlled substance orally in the treatment of an addict for addiction to a controlled substance:

(1) A psychiatric technician licensed pursuant to Chapter 10 (commencing with Section 4500) of Division 2 of the Business and Professions Code.

(2) A vocational nurse licensed pursuant to Chapter 6.5 (commencing with Section 2840) of Division 2 of the Business and Professions Code.

(3) A pharmacist licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.

(c) Except as permitted in this section, no person shall order, permit, or direct any other person to administer a narcotic controlled substance to a person being treated for addiction to a controlled substance.

11217. Authorized Place of Treatment

Except as provided in Section 11223, no person shall treat an addict for addiction to a narcotic drug except in one of the following:

(a) An institution approved by the State Department of Health Care Services, and where the patient is at all times kept under restraint and control.

(b) A city or county jail.

(c) A state prison.

(d) A facility designated by a county and approved by the State Department of Health Care Services pursuant to Division 5 (commencing with Section 5000) of the Welfare and Institutions Code.

(e) A state hospital.

(f) A county hospital.

(g) A facility licensed by the State Department of Health Care Services pursuant to Division 10.5 (commencing with Section 11750).

(h) A facility as defined in subdivision (a) or (b) of Section 1250 and Section 1250.3.

A narcotic controlled substance in the continuing treatment of addiction to a controlled substance shall be used only in those programs licensed by the State Department of Health Care Services pursuant to Article 1 (commencing with Section 11839) of Chapter 10 of Part 2 of Division 10.5 on either an inpatient or outpatient basis, or both.

This section does not apply during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age.

Neither this section nor any other provision of this division shall be construed to prohibit the maintenance of a place in which persons seeking to recover from addiction to a controlled substance reside and endeavor to aid one another and receive aid from others in recovering from that addiction, nor does this section or this division prohibit that aid, provided that no person is treated for addiction in a place by means of administering, furnishing, or prescribing of controlled substances. The preceding sentence is declaratory of preexisting law.

Neither this section or any other provision of this division shall be construed to prohibit short-term narcotic detoxification treatment in a controlled setting approved by the director and pursuant to rules and regulations of the director.

Facilities and treatment approved by the director under this paragraph shall not be subject to approval or inspection by the Medical Board of California, nor shall persons in those facilities be required to register with, or report the termination of residence with, the police department or sheriff's office.

11217.5. Administration in Office or Medical Facility of Non-Narcotic Drugs

Notwithstanding the provisions of Section 11217, a licensed physician and surgeon may treat an addict for addiction in any office or medical facility which, in the professional judgment of such physician and surgeon, is medically proper for the rehabilitation and treatment of such addict. Such licensed physician and surgeon may administer to an addict, under his direct care, those medications and therapeutic agents which, in the judgment of such physician and surgeon, are medically necessary, provided that nothing in this section shall authorize the administration of any narcotic drug.

11218. Limitation on Narcotics in First 15 Days of Treatment

A physician treating an addict for addiction may not prescribe for or furnish to the addict more than any one of the following amounts of controlled substances during each of the first 15 days of that treatment:

- (a) Eight grains of opium.
- (b) Four grains of morphine.
- (c) Six grains of Pantopon.
- (d) One grain of Dilaudid.
- (e) Four hundred milligrams of isonipecaine (Demerol).

11219. Limitation on Narcotics after First 15 Days of Treatment

After 15 days of treatment, the physician may not prescribe for or furnish to the addict more than any one of the following amounts of controlled substances during each day of the treatment:

- (a) Four grains of opium.
- (b) Two grains of morphine.
- (c) Three grains of Pantopon.
- (d) One-half grain of Dilaudid.
- (e) Two hundred milligrams of isonipecaine (Demerol).

11220. Required Discontinuance of Controlled Substances, Except Methadone or LAAM, After 30 Days

At the end of 30 days from the first treatment, the prescribing or furnishing of controlled substances, except methadone or LAAM, shall be discontinued.

11222. Persons in Custody: Treatment for Withdrawal Symptoms; Continued Participation in Narcotic Treatment Programs

In any case in which a person is taken into custody by arrest or other process of law and is lodged in a jail or other place of confinement, and there is reasonable cause to believe that the person is addicted to a controlled substance, it is the duty of the person in charge of the place of confinement to provide the

person so confined with medical aid as necessary to ease any symptoms of withdrawal from the use of controlled substances.

In any case in which a person, who is participating in a narcotic treatment program, is incarcerated in a jail or other place of confinement, he or she shall, in the discretion of the director of the program, be entitled to continue in the program until conviction.

Article 3. Veterinarians

11240. Prohibition on Prescribing, etc. Controlled Substance for Human Being

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

11241. Prescription Contents

A prescription written by a veterinarian shall state the kind of animal for which ordered and the name and address of the owner or person having custody of the animal.

Article 4. Sale Without Prescription

11250. Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form

(a) No prescription is required in case of the sale of controlled substances at retail in pharmacies by pharmacists to any of the following:

- (1) Physicians.
- (2) Dentists.
- (3) Podiatrists.
- (4) Veterinarians.

(5) Pharmacists acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurses acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistants acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107.

- (6) Optometrist.

(b) In any sale mentioned in this article, there shall be executed any written order that may otherwise be required by federal law relating to the production, importation, exportation, manufacture, compounding, distributing, dispensing, or control of controlled substances.

11251. Authorized Wholesale by Pharmacists

No prescription is required in case of sales at wholesale by pharmacies, jobbers, wholesalers, and manufacturers to any of the following:

- (a) Pharmacies as defined in the Business and Professions Code.
- (b) Physicians.
- (c) Dentists.
- (d) Podiatrists.
- (e) Veterinarians.
- (f) Other jobbers, wholesalers or manufacturers.
- (g) Pharmacists acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurses acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistants acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107.
- (h) Optometrists.

11252. Preservation of Federally Required Form

All wholesale jobbers, wholesalers, and manufacturers, mentioned in this division shall keep, in a manner readily accessible, the written orders or blank forms required to be preserved pursuant to federal law relating to the production, importation, exportation, manufacture, compounding, distributing, dispensing, or control of controlled substances.

11253. Duration of Retention

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

11255. Actions Constituting Sale

The taking of any order, or making of any contract or agreement, by any traveling representative or employee of any person for future delivery in this state, of any controlled substance constitutes a sale within the meaning of this division.

11256. Required Report of Order by or Sale to Out-of-State Wholesaler or Manufacturer

Within 24 hours after any purchaser in this state gives any order for a controlled substance classified in Schedule II to, or makes any contract or agreement for purchases from or sales by, an out-of-state wholesaler or manufacturer of any controlled substances for delivery in this state, the purchaser shall forward to the Attorney General by registered mail a true and correct copy of the order, contract, or agreement.

11364. Possession of Illegal Drug Paraphernalia

(a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e) or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section

11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance that is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Until January 1, 2021, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

DIVISION 105. COMMUNICABLE DISEASE PREVENTION AND CONTROL

CHAPTER 13. ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) IMMUNIZATION

121281. Board Web Site: Testing for HIV and Viral Hepatitis; Disposal of Sharps Waste; How to Access Drug Treatment

In order to assist pharmacists and pharmacy personnel in the education of consumers who are at risk of bloodborne infections regarding methods and opportunities for improving and protecting their health, and thereby protect the public health, the Office of AIDS shall develop and maintain all of the following information, on its Internet Web site, and the California State Board of Pharmacy shall also post, or maintain a link to, the information on its Internet Web site:

(a) How consumers can access testing and treatment for HIV and viral hepatitis.

(b) How consumers can safely dispose of syringes and hypodermic needles or other sharps waste.

(c) How consumers can access drug treatment.

CHAPTER 13.5. DISEASE PREVENTION DEMONSTRATION PROJECT

121285. The Disease Prevention Demonstration Project; Furnishing or Sale of Nonprescription Hypodermic Needles or Syringes

(a) The Disease Prevention Demonstration Project, a collaboration between pharmacies and local and state health officials, is hereby authorized for the purpose of evaluating the long-term desirability of allowing licensed

pharmacists to furnish or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

(b) The State Department of Health Services shall evaluate the effects of allowing pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription. The State Department of Health Services is encouraged to seek funding from private and federal sources to pay for the evaluation.

(c) The State Department of Health Services shall convene an uncompensated evaluation advisory panel comprised of all of the following: two or more specialists in the control of infectious diseases; one or more representatives of the California State Board of Pharmacy; one or more representatives of independent pharmacies; one or more representatives of chain pharmacy owners; one or more representatives of law enforcement executives, such as police chiefs and sheriffs; one or more representatives of rank and file law enforcement officers; a specialist in hazardous waste management from the State Department of Health Services; one or more representatives of the waste management industry; and one or more representatives of local health officers.

(d) In order to furnish or sell nonprescription hypodermic needles or syringes as part of the Disease Prevention Demonstration Project in a county or city that has provided authorization pursuant to Section 4145 of the Business and Professions Code, a pharmacy shall do all of the following:

(1) Register with the local health department by providing a contact name and related information, and certify that it will provide, at the time of furnishing or sale of hypodermic needles or syringes, written information or verbal counseling on all of the following:

(A) How to access drug treatment.

(B) How to access testing and treatment for HIV and hepatitis C.

(C) How to safely dispose of sharps waste.

(2) Store hypodermic needles and syringes so that they are available only to authorized personnel, and not openly available to customers.

(3) In order to provide for the safe disposal of hypodermic needles and syringes, a registered pharmacy shall provide one or more of the following options:

(A) An onsite safe hypodermic needle and syringe collection and disposal program.

(B) Furnish or make available for purchase mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and provide tracking forms to verify destruction at a certified disposal facility.

(C) Furnish or make available for purchase personal sharps disposal containers that meet state and federal standards for disposal of medical waste.

(e) Local health departments shall be responsible for all of the following:

(1) Maintaining a list of all pharmacies within the local health department's jurisdiction that have registered under the Disease Prevention Demonstration Project.

(2) Making available to pharmacies written information that may be provided or reproduced to be provided in writing or orally by the pharmacy at the time of furnishing or the sale of nonprescription hypodermic needles or syringes, including all of the following:

- (A) How to access drug treatment.
- (B) How to access testing and treatment for HIV and hepatitis C.
- (C) How to safely dispose of sharps waste.
- (f) As used in this chapter, “sharps waste” means hypodermic needles, syringes, and lancets.

CHAPTER 18. CLEAN NEEDLE AND SYRINGE EXCHANGE PROGRAM

121349. Legislative Findings and Declaration

[A second like-numbered section follows.]

(a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Authorization shall be made after consultation with the local health officer and local law enforcement leadership, and after a period of public comment, as described in subdivision (e). In making the determination, the department shall balance the concerns of law enforcement with the public health benefits. The authorization shall not be for more than two years. Before

the end of the two-year period, the department may reauthorize the program in consultation with the local health officer and local law enforcement leadership.

(d) In order for an entity to be authorized to conduct a project pursuant to this chapter, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:

(1) The entity provides, directly or through referral, all of the following services:

(A) Drug abuse treatment services.

(B) HIV or hepatitis screening.

(C) Hepatitis A and hepatitis B vaccination.

(D) Screening for sexually transmitted infections.

(E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.

(F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.

(3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:

(A) Provide needles and syringe exchange services for all of its participants.

(B) Provide HIV and viral hepatitis prevention education services for all of its participants.

(C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:

(A) The total number of persons served.

(B) The total number of syringes and needles distributed, recovered, and disposed of.

(C) The total numbers and types of referrals to drug treatment and other services.

(e) If the application is provisionally deemed appropriate by the department, the department shall, at least 90 days prior to approval of the application, provide for a period of public comment as follows:

(1) Post on the department's Internet Web site the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.

(2) Send a written and an e-mail notice to the local health officer of the affected jurisdiction.

(3) Send a written and an e-mail notice to the chief of police, the sheriff, or both, as appropriate, of the jurisdictions in which the program will operate.

(f) The department shall establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to this chapter.

(g) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(h) This section shall become *inoperative on January 1, 2019*, and as of that date is repealed.

121349. Legislative Findings and Declaration

(a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(d) This section shall become *operative on January 1, 2019*.

121349.1. Needle and Syringe Exchange Project; Requirements

[A second like-numbered section follows.]

(a) The State Department of Public Health or a city, county, or a city and county with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes during participation in an exchange project. Program participants shall not be subject to criminal prosecution for possession of needles or syringes acquired from an authorized needle and syringe exchange project entity.

(b) This section shall become *inoperative on January 1, 2019*, and as of that date is repealed

121349.1. Needle and Syringe Exchange Project; Requirements

(a) A city, county, or a city and county, with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Public Health Service, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Providers participating in an exchange project authorized by the county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for possession of needles or syringes during participation in an exchange project.

(b) This section shall become *operative on January 1, 2019*.

121349.2. Local, Health and Law Enforcement Comment Biennially, Public Input [A second like-numbered section follows.]

(a) Local government, local health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become *inoperative on January 1, 2019*, and as of that date is repealed.

121349.2. Local, Health and Law Enforcement Comment Annually, Public Input

(a) Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on an annual basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare from clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become *operative on January 1, 2019*.

121349.3. Biennial Report of Health Officer of Participating Jurisdiction [A second like-numbered section follows.]

(a) The health officer of the participating jurisdiction shall present biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this biennial meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and

ordinances, and as local officials deem appropriate. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local health officer based on the reports to the department from service providers within the jurisdiction of that local health officer.

(b) This section shall become *inactive on January 1, 2019*, and as of that date is repealed.

121349.3. Annual Report of Health Officer of Participating Jurisdiction

(a) The health officer of the participating jurisdiction shall present, annually at an open meeting of the board of supervisors or city council, a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate.

(b) This section shall become *operative on January 1, 2019*.

DIVISION 106. PERSONAL HEALTH CARE

PART 4.5. PAIN PATIENT'S BILL OF RIGHTS

124960. Treatment of Severe Chronic Intractable Pain

The Legislature finds and declares all of the following:

- (a) The state has a right and duty to control the illegal use of opiate drugs.
- (b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.
- (c) For some patients, pain management is the single most important treatment a physician can provide.
- (d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.
- (e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.
- (f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain and severe chronic intractable pain can be safe.
- (g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who treat severe chronic intractable pain with methods that include the use of opiates.

124961. Pain Patient's Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient who suffers from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve that pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who treat pain and whose methods include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain, as long as that prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

DIVISION 106. PERSONAL HEALTH CARE

PART 5. HEREDITARY DISEASES/CONGENITAL DEFECTS CHAPTER 2. GENETIC DISEASE SERVICES

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.10.

This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.15. Legislative Declarations

The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors has provided people with hemophilia and other bleeding disorders the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations according to the federal Centers for Disease Control

and Prevention and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.

(h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.20. Definitions

Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

(a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(c) "Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that, without treatment, result in uncontrollable bleeding or abnormal blood clotting.

(d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, factor VII, factor VIIa, factor VIII, and factor IX products, von Willebrand factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) "Emergency" means care as defined in Section 1317.1.

(f) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the factor I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and

Services Administration (HRSA) of the United States Department of Health and Human Services.

(h) “Home use” means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

(i) “Patient” means a person needing a blood clotting product for home use.

(j) (1) “Provider of blood clotting products for home use” means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

(2) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.25. Requirements for Providers of Blood Clotting Products for Home Use

Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders 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.

(c) Maintain 24-hour on-call service seven days a week for every day of the year, adequately screen telephone calls for emergencies, acknowledge all telephone calls within one hour or less, and have access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.

(d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) 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.

(e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(g) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(h) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver 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.

(i) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(j) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(k) Provide language interpretive services over the telephone or in person, as needed by the patient.

(l) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(m) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(n) Comply with the privacy and confidentiality requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.30. Administration and Enforcement

The California State Board of Pharmacy shall administer and enforce this article.

125286.35. Exemptions

Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood clotting products for home use.

DIVISION 116. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION

CHAPTER 2. HEALTH FACILITIES

150200. Legislative Intent to Establish Voluntary Drug Repository and Distribution Program

It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. It is also the intent of the Legislature that the health and safety of Californians are protected and promoted through this program, while reducing unnecessary waste at licensed health and care facilities, by allowing those facilities to donate unused and unexpired medications that were never in the hands of a patient or resident and for which no credit or refund to the patient or resident could be received.

150201. Definitions

(a) “Donor organization” means an entity described in subdivision (a) of Section 150202.

(b) “Eligible entity” means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.

(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

(c) “Medication” or “medications” means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(d) “Participating entity” means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

150202. Authorized Donations of Unused Medications

(a) Notwithstanding any other law, a donor organization is defined, for purposes of this division, to refer to one of the following health and care facilities that may donate centrally stored unused medications under a program established pursuant to this division:

- (1) A licensed general acute care hospital, as defined in Section 1250.
- (2) A licensed acute psychiatric hospital, as defined in Section 1250.
- (3) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.
- (4) A licensed intermediate care facility, as defined in Section 1250.
- (5) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.
- (6) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.
- (7) A licensed correctional treatment center, as defined in Section 1250.
- (8) A licensed psychiatric health facility, as defined in Section 1250.2.
- (9) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.
- (10) A licensed residential care facility for the elderly, as defined in Section 1569.2, with 16 or more residents.
- (11) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

(b) Medication donated by health and care facilities pursuant to subdivision (a) shall meet the requirements of subdivisions (c) and (d) of Section 150204 and shall be unexpired medication that would have otherwise been destroyed by the facility or another appropriate entity.

(c) Medication eligible for donation by the health and care facilities pursuant to subdivision (a) shall be directly delivered from the dispensing pharmacy, wholesaler or manufacturer, to the health or care facility and subsequently centrally stored. Centrally stored medication that originated from a patient or resident is not eligible for donation under this division.

150202.5. Authorized Donations of Unused Medications; Manufacturer Medications

Notwithstanding any other law, a pharmacy, licensed in California and not on probation with the California State Board of Pharmacy, whose primary or sole type of pharmacy practice type is limited to a skilled nursing facility, home health care, board and care, or mail order, may donate unused, unexpired medication that meets the requirements of subdivisions (c) and (d) of Section 150204, under a program established pursuant to this division and that meets either of the following requirements:

- (a) The medication was received directly from a manufacturer or wholesaler.
- (b) The medication was returned from a health facility to the issuing pharmacy, in a manner consistent with state and federal law.

150203. Drug Wholesalers or Manufacturers May Donate Unused Medications

Notwithstanding any other provision of law, a wholesaler licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code and a drug manufacturer that is legally authorized under federal law to manufacture and sell pharmaceutical drugs may

donate unused medications under the voluntary drug repository and distribution program established by a county pursuant to this division.

150204. County May Establish Repository and Distribution Program for Dispensing Donated Drugs

(a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in Section 150201, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

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

(i) (1) Except as provided in paragraph (2), medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(2) A pharmacy that exists solely to operate the repository and distribution program may repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date.

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

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

150205. Liability

(a) The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(1) A prescription drug manufacturer, wholesaler, governmental entity, or participating entity.

(2) A pharmacist or physician who accepts or dispenses prescription drugs.

(3) A licensed health or care facility, as described in Section 150202, or a pharmacy, as described in Section 150202.5.

(b) A surplus medication collection and distribution intermediary, as described in Section 150208, shall not be subject to criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with this division.

150206. No Immunity for Noncompliance or Negligence

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

150207. Disciplinary Actions

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