DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

PROPOSED REGULATORY LANGUAGE
Self-Assessments and Standard of Care

Legend:	Added text is indicated with an underline. Omitted text is indicated by (* * * *) Deleted text is indicated by ~~strikeout~~.

Repeal sections 1715 and 1715.1 of Division 17 of Title 16 of the California Code of Regulations:

~~§ 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) A pharmacist-in-charge of a community pharmacy shall assess the pharmacy's compliance with current laws and regulations by using the components of Form 17M-13 (Rev. 1/22) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." As used in this section, a community pharmacy means a pharmacy serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers shall assess compliance with current laws and regulations using the components of Form 17M-14 (Rev. 01/22) entitled "Hospital Pharmacy Self-Assessment." Both forms are hereby incorporated by reference, and contain the following components:~~

~~(1) The pharmacist-in-charge shall provide identifying information about the~~

~~pharmacy including:~~

~~(A) Name and any license number(s) of the pharmacy and their expiration date(s);~~

~~(B) Address, phone number, ownership type, and website address, if applicable, of the pharmacy;~~

~~(C) Federal Drug Enforcement Agency (DEA) registration number, its expiration date, and date of most recent DEA inventory;~~

~~(D) Hours of operation of the pharmacy; and~~

~~(E) Accreditation by third party, if applicable, and dates of accreditation.~~

~~(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.~~

~~(3) The pharmacist-in-charge shall respond "yes", "no," or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.~~

~~(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.~~

~~(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials on the self-assessment.~~

~~(6) The pharmacist-in-charge shall certify on the final page of the self-assessment that they have completed the self-assessment of the pharmacy of which they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature on the self-assessment.~~

~~(7) The pharmacy owner or hospital administrator shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of~~

the laws of the State of California with an original handwritten signature on the self-assessment.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

NOTE: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333, Business and Professions Code.

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 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 annually before July 1 of every 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 automated drug delivery system license has been issued.

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.

(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) entitled “Automated Drug Delivery System Self-Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.

(1) The pharmacist-in-charge shall provide identifying information about the

~~underlying operating pharmacy including:~~

~~(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);~~

~~(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;~~

~~(C) DEA registration number, expiration date, and date of most recent DEA inventory;~~

~~(D) Hours of operation of the pharmacy; and~~

~~(E) ADDS license number, address, and hours of operation.~~

~~(2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.~~

~~(3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.~~

~~(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.~~

~~(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.~~

~~(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system's license issued by the board. This certification shall be made under~~

~~penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.~~

~~(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.~~

~~(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.~~

~~Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4 and 4427.5, Business and Professions Code; and Section 16.5, Government Code.~~

Amend sections 1732.5, 1735.1 and 1736.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacists.

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

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal ("required CE hours") shall be completed by participation in a Board provided CE course in Law and Ethics. At least one (1) hour of the required CE hours shall be completed by participating in a cultural competency course from an accreditation agency approved by the Board pursuant to section 1732.05, covering the specified content areas as required by section 4231 of the Business and Professions Code.

~~(c) Pharmacists providing specialized patient-care services, as identified in subsections (c)(1)-(4) below, shall complete specialized CE (as part of the required CE hours) as follows:~~

~~(1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by section 4052.9 of the Business and Professions Code, if applicable.~~

~~(2) At least two (2) hours of approved CE specific to travel medicine, as set forth in section 1746.5 of this Article, if applicable.~~

~~(3) At least one (1) hour of approved CE specific to emergency contraception drug therapy, as required by Business and Professions section 4052.3, if applicable.~~

~~(4) At least one (1) hour of approved CE specific to immunizations and vaccinations, as set forth in section 1746.4 of this Article, if applicable.~~

(~~d~~c) Pharmacists who prescribe any Schedule II controlled substances (as defined in Health and Safety Code section 11055) shall complete at least one (1) hour of the required CE hours by participating in a Board approved CE course once every four (4) years on the risks of addiction associated with the use of Schedule II drugs, as required by section 4232.5 of the Business and Professions Code.

(~~e~~d) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course to demonstrate compliance with the provisions of this section.

(~~f~~e) "Board approved CE course" shall mean coursework from a provider meeting the requirements of section 1732.1.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections ~~4052.3, 4052.8, 4052.9,~~ 4231, 4232 and 4232.5, Business and Professions Code.

§ 1735.1. Introduction and Scope.

In addition to the standards in USP Chapter 795 and section 353a of title 21, United States Code, the compounding of a CNSP that is performed by or through a licensee of the Board shall meet the following requirements of this article.

(a) Nonsterile compounding is performed by or under the direct supervision and control of a licensed pharmacist pursuant to a patient specific prescription, unless otherwise specified in this article.

(b) Reconstitution of a conventionally manufactured drug product that is not done in accordance with the FDA approved directions is considered compounding.

(c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient

populations.

(d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of no more than a 14-day supply, for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.

(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:

(1) is essentially a copy of one or more commercially available drug products, unless:

(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding or within 60 days of the end of the shortage, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or

(B) the pharmacist verifies and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient.

(C) Documentation describing the conditions in (1)(A) and (1)(B) is maintained in a readily retrievable format.

(2) is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian acting within a valid veterinarian-client-patient relationship (VCPR) determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 -- Compounding Animal Drugs from Bulk Drug Substances issued August 2022, which is hereby incorporated by reference.

~~(f) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.~~

(~~g~~f) In addition to the provisions in section 1707.2, consultation includes proper use, storage, handling, and disposal of the CNSP and related supplies furnished.

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 compounded 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 compounded medications that meets the requirements of Business and Professions Code Section 4074.

(~~h~~g) CNSPs with human whole blood or human whole blood derivatives shall be compounded in compliance with Health and Safety Code section 1602.5.

(~~i~~h)A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 - 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.

Note: Authority cited: Sections 4005 and 4126.8, Business and Professions Code. Reference: Sections 4005, 4051, 4052, 4076, 4081, 4105, 4126.8, 4169, 4301, 4306.5 and 4332, Business and Professions Code; Section 355, Title 21 United States Code; and Part 530, Title 21, Code of Federal Regulations.

§ 1736.1. Introduction and Scope.

In addition to the standards set forth in USP Chapter 797 and 353a of title 21, United States Code, the following requirements of this article apply to the compounding of a CSP that is performed by or through a licensee of the Board.

(a) For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.

(b)(1) Except as allowed in paragraphs (2) and (3), CSPs for direct and immediate administration as provided in USP Chapter 797 shall only be compounded in those

limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available.

(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures shall be documented in accordance with facility's SOP. Failures requiring use of immediate use provisions shall be reported to the Board within 72 hours of the transition to immediate use provisions.

(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in section 1395i-4(c)(2)(B) of title 42, United States Code, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs. Failures requiring use of immediate use provisions shall be reported to the Board within 72 hours of the transition to immediate use provisions.

(c) Notwithstanding subdivision (a), a limited quantity of CSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for identified patients based on a documented history of prescriptions for that patient population.

(d) A reasonable quantity of a CSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of not more than a 7-day supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.

(A) With the exception of a topical ophthalmic where up to a 28-day supply may be furnished to veterinarian's office for an individual patient. Such topical ophthalmics shall be compliant with USP Chapter 797 section 14.5, Multiple-Dose CSPs.

(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that:

(1) is essentially a copy of one or more commercially available drug products, unless:

(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or

(B) the pharmacist verifies and documents that the preparation produces a clinically significant difference based on the medical need of an identified individual patient.

(C) Documentation describing the conditions in subsections (1)(A) and (1)(B) is maintained in a readily retrievable format.

(2) is made with any component not suitable for use in a CSP for the intended veterinary population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR) determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compounding shall be done in compliance with the Center for Veterinary Medicine Guidance for Industry #256 -- Compounding Animal Drugs from Bulk Drug Substances issued in August 2022, which is hereby incorporated by reference.

(3) is made with a non-sterile component for which a conventionally manufactured sterile component is available unless the CSP master formula supports such use and is appropriate for the intended CSP.

(4) requires end product sterilization unless sterilization occurs within the same licensed compounding location.

~~(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-~~

~~in-charge shall complete a self-assessment consistent with the requirements established in section 1715.~~

(~~g~~f) In addition to the provisions in Section 1707.2 of this Division, consultation includes proper use, storage, handling and disposal of the CSP and related supplies furnished. 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 compounded medications that meets the requirements of Business and Professions Code Section 4074.

(~~h~~g) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5. This shall not apply to the compounding of an FDA-approved human whole blood or human whole blood derivative product.

Note: Authority cited: Sections 4005, 4126.8 and 4127, Business and Professions Code.
Reference: Sections 4005, 4123, 4126.8, 4127.1 and 4127.2, Business and Professions Code; and Section 353a, Title 21, United States Code.

Repeal sections 1746, 1746.1, 1746.2, 1746.3, 1746.4, 1746.5, 1747, and 1784 of Division 17 of Title 16 of the California Code of Regulations:

~~**§ 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			
Brand	***Tablets per Dose***	***Ethinyl Estradiol***	***Levonorgestrel***
	(two doses 12 hours apart*)	***Per dose (mcg)***	***per dose (mg)****
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

Non-Prescription Drugs	*Dose*	*Timing of Administration*
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 period?	//	
2a	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
2b	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
2c	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it	Yes ☐	No ☐

	makes it hard to be in light, or it involves numbness?		
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19a	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
19b	If yes, list them here:		
20a	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
20b	If yes, list them here:		

Note: Authority cited: 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.

(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~~

Rx for Change

Nicotine Replacement Therapy Medications for Smoking Cessation

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

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

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

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

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

Copyright © 1999–2015 The Regents of the University of California. All rights reserved. Updated January 26, 2015.

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 Opioid Antagonists.

A pharmacist furnishing an opioid antagonist for overdose reversal 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 an opioid antagonist is furnished.

(b) Training. Prior to furnishing an opioid antagonist, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent curriculum-based training program, completed in a Board recognized school of pharmacy, specific to the use of opioid antagonists for overdose reversal.

(c) Protocol for Pharmacists Furnishing Opioid Antagonists. Before providing an opioid antagonist, the pharmacist shall:

(1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist furnished.

(2) When an opioid antagonist 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 the opioid antagonist furnished.

(3) 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 also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(4) Labeling: A pharmacist shall label the opioid antagonist consistent with law and regulations.

(5) Notifications:

At the request of the patient, a pharmacist shall notify the identified primary care provider, if any, of the product furnished or enter appropriate information in a shared patient record system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, the pharmacist shall provide the patient a written record of the drug furnished along with a recommendation for the patient to consult with an appropriate health care provider of the patient's choice.

Note: Authority cited: Sections 4005 and 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 any vaccine pursuant to section 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: A pharmacist must complete one hour of continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: At the request of a patient, a pharmacist shall notify each patient's

primary care provider of any vaccine 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 a 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. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3), of the Business and Professions Code, the information described in section 120440, subdivision (c), of the Health and Safety Code within 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subdivision (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 information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide each patient with a vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052, 4052.8 and 4081, Business and Professions Code; Section 120440, Health and Safety Code; and Section 300aa-25, Title 42, United States Code.

§ 1746.5. Pharmacists Furnishing Travel Medications.

(a) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10)(A)(3) of the Business and Professions Code (hereafter, “travel medications”) shall follow the requirements of this section.

(b) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), a prescription medication “not requiring a diagnosis” means a prescription medication that is either:

(1) For treatment of a condition that is recognized as both self-diagnosable and self-treatable by the CDC's Health Information for International Travel (commonly called the Yellow Book), or

(2) For prophylaxis of a condition.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization training program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(2) Completion of a travel medicine training program, which must consist of at least 10 hours of training and cover each element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012), hereby incorporated by reference,

(3) Completion of the CDC Yellow Fever Vaccine Course, and

(4) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medications, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of the patient's travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient within 14 days of the date of furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic

manner such that the information required under section 300aa-25 of title 42 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 written document that reflects the clinical assessment and travel medication plan.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the Board, provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(A) HIV preexposure and postexposure prophylaxis pharmacology.

(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(D) Patient referral resources and supplemental resources for pharmacists.

(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).

(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation of training maintained pursuant to this subdivision must be made available upon request of the Board.

(c) For the purposes of this section, documentation of preexposure prophylaxis furnished and services provided shall be maintained in patient records, in the record system maintained by the pharmacy, for a minimum of three years from the date when the preexposure prophylaxis was furnished. Such records shall be made available upon request of the Board, consistent with the provisions of Business and Professions Code sections 4081 and 4105.

Note: Authority cited: Sections 4005, 4052.02 and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, 4052.03, 4081 and 4105, Business and Professions Code; and Section 120972, Health and Safety Code.

§ 1784. Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-In-Charge or Responsible Manager.

(a) Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, 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 or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new license is issued.

(2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete the "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 12/21) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name, license number of the premises, and the license expiration date;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into

~~compliance with the law.~~

~~(5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.~~

~~(6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:~~

~~(A) They have completed the self-assessment of the licensed premises for which they are responsible;~~

~~(B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;~~

~~(C) They understand that all responses are subject to verification by the Board of Pharmacy; and~~

~~(D) The information provided in the self-assessment form is true and correct.~~

~~(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and understand that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.~~

~~(d) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.~~

~~(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.~~

~~(f) Any identified areas of noncompliance shall be corrected as specified in the certification.~~

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4043, 4044.5, 4045, 4053, 4053.1, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.~~