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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

LEGISLATION AND REGULATION COMMITTEE
CHAIR REPORT

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

Attachment 1

1. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Summary of Regulation: This proposal amends the Board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

Status: Board adopted June 21, 2019. Formal review by OAL began on December 11, 2019. The rulemaking package was approved by OAL on January 27, 2020 and became law on April 1, 2020. The Board's website has been updated with the revised language. Additionally, a subscriber alert was sent to the regulated public to notify them of the approval of the amended regulation text.

The Board adopted language can be found on the Board's website:
https://www.pharmacy.ca.gov/laws_regs/approved_regs.shtml

b. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

Attachment 2

1. Proposed Regulation to Amend Title 16 CCR Section 1707.2 Related to Duty to Consult

Summary of Regulation: This proposal amends the Board's regulations regarding the duty to provide consultation for mail-order pharmacies.

Status: Board adopted November 6, 2019. Formal review by OAL began on March 6, 2020. Due to COVID-19, OAL's review deadline has been extended by up to 60 days. OAL's final review date is now June 19, 2020.

The Board adopted language can be found on the Board's website:
https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml

2. Proposed Regulation to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Summary of Regulation: This proposal updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application. The proposal will also reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

Status: Board adopted November 6, 2019. Formal review by OAL began on March 3, 2020. Due to COVID-19, OAL's review deadline has been extended by up to 60 days. OAL's final review date is now June 14, 2020.

The Board adopted language can be found on the Board's website:
https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml

3. Emergency Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

Summary of Regulation: This proposal, on an emergency basis, establishes the criteria for the training programs required for pharmacists to independently initiate and furnish preexposure and postexposure prophylaxis.

Status: Board adopted January 29, 2020. Formal review by OAL began on April 20, 2020 and ends on May 1, 2020. An update will be provided at the Board meeting.

The Board adopted language can be found on the Board's website:
https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml

c. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Attachment 3

Provided below is a summary of each of the regulations currently undergoing pre-notice review. As there are many steps included in the pre-review process, the status is detailed below. Members have previously requested that regulations without action for over 30 days

be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**. The full timelines for each of the regulation are included in **Attachment 3**.

1. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

   Summary of Regulation: This proposal establishes regulatory requirements for automated refill programs.

   Status: Approved by DCA and Submitted to Agency for Formal Review: January 9, 2020. Board staff has received the proposed text back and anticipates resubmitting the document to Agency in early May 2020.

2. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Summary of Regulation: This proposal amends the Board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

   Status: Re-submitted to DCA for Pre-Notice Review: January 14, 2020

3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

   Summary of Regulation: This proposal establishes the regulatory framework for third-party logistics providers.

   Status: Approved by DCA and Submitted to Agency for Formal Review: February 12, 2020

4. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

   Summary of Regulation: This proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

   Status: Submitted to DCA for Pre-Notice Review: December 24, 2018

   The Board approved self-assessment forms can be found on the Board's website: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml

5. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

   Summary of Regulation: This proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

   Status: Submitted to DCA for Pre-Notice Review: December 26, 2018

   The Board approved self-assessment forms can be found on the Board's website: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml

6. Proposed Regulations to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of Receipt and Delivery of Prescriptions and Prescription Medications, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112

   Summary of Regulation: This proposal will require submission of quality assurance records to the Board, update the Board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form.

   Status: Approved by DCA and Submitted to Agency for Formal Review: April 17, 2020.

7. Proposed Permanent Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

   Summary of Regulation: This proposal, on a permanent basis, establishes the criteria for the training programs required so that pharmacists may independently initiate and furnish preexposure and postexposure prophylaxis.

   Status: Submitted to DCA for Pre-Notice Review: February 7, 2020

d. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Attachment 4

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Summary of Regulation: This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

Status: **Returned to the Board on December 12, 2019. Board staff is working on amendments to the package to integrate AB 2138 and the substantial relationship/rehabilitation criteria. Board staff anticipates resubmitting the rulemaking package to DCA in May 2020.**

2. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

Summary of Regulation: This proposal amends the drug loss reporting requirements to further define when drug losses must be reported to the Board and will provide greater clarity for the regulated public.

Status: Board approved January 29, 2020. Board staff is drafting the rulemaking documents and anticipates submitting the rulemaking package to DCA for pre-notice review in early June 2020.

3. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

Summary of Regulation: This proposal amends and clarifies the requirements for the completion of the inventory reconciliation report.

Status: Board approved January 29, 2020. Board staff is drafting the rulemaking documents and anticipates submitting the rulemaking package to DCA for pre-notice review in late May 2020.

Attachment 1

Regulation Timeline

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

1. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Timeline:
Approved by Board: May 4, 2017
Submitted to DCA for Pre-Notice Review: May 31, 2017
Returned to the Board: January 18, 2018
Modified language approved by Board: March 27, 2018
Re-submitted to DCA for Pre-Notice Review: June 13, 2018
Returned to the Board on: July 2, 2018
Re-submitted to DCA for Pre-Notice Review: July 2, 2018
Formal DCA Pre-Notice Review began: July 2, 2018
45-Day Comment Period began: April 26, 2019 and Closed on June 17, 2019
Adopted by Board: June 21, 2019
Submitted to DCA for Formal Review: August 28, 2019
Submitted to OAL for Formal Review: December 11, 2019
Approved by OAL on January 27, 2020
Effective Date: April 1, 2020

Naloxone Fact Sheet
16 CCR § 1746.3

BOARD OF PHARMACY

Order of Adoption

Proposal to amend § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

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 or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available

on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

(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 cited: Section 4052.01, Business and Professions Code.
Reference: Section 4052.01, Business and Professions Code.

Attachment 2

Regulation Timeline

b. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

   Timeline:
   Approved by Board: May 2, 2018
   Submitted to DCA for Pre-Notice Review: July 23, 2018
   Returned to the Board on: August 23, 2018
   Re-submitted to DCA for Pre-Notice Review: September 14, 2018
   Formal DCA Pre-Notice Review began: October 1, 2018
   45-Day Comment Period: August 16, 2019 to September 30, 2019
   Adopted by the Board: November 6, 2019
   Submitted to DCA for Formal Review: December 17, 2019
   Submitted to OAL for Final Review: March 6, 2020
   OAL decision due by June 19, 2020

2. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

   Timeline:
   Approved by Board: February 6, 2018
   Submitted to DCA for Pre-Notice Review: July 2, 2018
   Formal DCA Pre-Notice Review began: August 3, 2018
   45-Day Comment Period: August 30, 2019 to October 14, 2019
   Adopted by the Board: November 6, 2019
   Submitted to DCA for Formal Review: December 11, 2019
   Submitted to OAL for Final Review: March 3, 2020
   OAL decision due by June 14, 2020

3. Emergency Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

   Timeline:
   Approved by Board: January 29, 2020
   Submitted to DCA for Pre-Notice Review: February 7, 2020
   Formal DCA Pre-Notice Review began: February 26, 2020
   Noticed by OAL (5-day comment period): April 20, 2020
   OAL decision due by May 1, 2020

Mail-Order Pharmacy Consultation
16 CCR § 1707.2

Title 16. Board of Pharmacy

Amend section 1707.2 in Article 2 of Division 17 of Title 16 California Code of Regulations to read as follows:

§ 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:~~

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

(4~~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.

(b)(1~~2~~) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail, or delivery), a pharmacy shall ensure that ~~the patient receives written notice~~:

(A) the patient receives written notice of his or her right to request consultation; ~~and~~

(B) the patient receives written notice of ~~a~~ the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record~~.~~; and

(C)A pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(2~~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.

Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code. Reference: Sections 4005, 4076, 4112 and 4122, Business and Professions Code.

Abandonment of Applications
16 CCR § 1706.2

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1706.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1706.2. Abandonment of Application Files.

(a) An applicant for a premises 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.~~

(b ~~c~~) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f)(1) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall 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.

(c ~~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.

(d ~~e~~) An applicant for an 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.

(e) An applicant for an individual license not included in subdivision (b), (c), or (d), 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.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, ~~and~~ 4208, and 4210, Business and Professions Code.

Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
16 CCR § 1747 (Emergency)

Title 16. Board of Pharmacy
Proposed Text

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 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 or provided by a provider accredited by an approved accreditation agency that satisfies 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 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. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

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

Attachment 3

Regulation Timeline

c. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

   Timeline:
   Approved by Board: May 3, 2017
   Submitted to DCA for Pre-Notice Review: November 7, 2017
   Returned to the Board on: March 26, 2018
   Re-submitted to DCA for Pre-Notice Review: June 29, 2018
   Returned to the Board on: August 20, 2018
   Re-submitted to DCA for Pre-Notice Review: September 20, 2018
   Submitted to Agency for Pre-Notice Review: January 9, 2020

2. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Timeline:
   Approved by Board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: January 26, 2017
   Returned to the Board on: March 28, 2017
   Re-submitted to DCA for Pre-Notice Review: May 24, 2018
   Returned to the Board: August 6, 2018
   Re-submitted to DCA for Pre-Notice Review: August 16, 2018
   Returned to the Board: November 2, 2018
   Re-submitted to DCA for Pre-Notice Review: December 20, 2018
   Returned to the Board: January 6, 2020
   Re-submitted to DCA for Pre-Notice Review: January 14, 2020

3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

   Timeline:
   Approved by Board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: February 9, 2017
   Returned to the Board on: February 28, 2017
   Re-submitted to DCA for Pre-Notice Review: October 25, 2017
   Returned to the Board on: March 26, 2018
   Re-submitted to DCA for Pre-Notice Review: June 28, 2018
   Returned to the Board on: August 28, 2018
   Re-submitted to DCA for Pre-Notice Review: September 6, 2018
   Returned to the Board on: October 30, 2018
   Re-submitted to DCA for Pre-Notice Review: December 20, 2018
   Submitted to Agency for Pre-Notice Review: February 12, 2020

4. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

   Timeline:
   Approved by Board: November 8, 2017
   Submitted to DCA for Pre-Notice Review: February 2, 2018
   Returned to the Board on: April 17, 2018
   Re-submitted to DCA for Pre-Notice Review: July 23, 2018
   Returned to the Board on: November 13, 2018
   Re-submitted to DCA for Pre-Notice Review: December 24, 2018

5. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

   Timeline:
   Approved by Board: November 8, 2017
   Submitted to DCA for Pre-Notice Review: December 26, 2018

6. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

   Timeline:
   Approved by Board: January 30, 2019
   Submitted to DCA for Pre-Notice Review: April 30, 2019
   Returned to the Board on: December 17, 2019
   Re-submitted to DCA for Pre-Notice Review: December 20, 2019
   Formal DCA Pre-Notice Review began: December 23, 2019
   Submitted to Agency for Pre-Notice Review: April 17, 2020

7. Proposed Permanent Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

   Timeline:
   Approved by Board: January 29, 2020
   Submitted to DCA for Pre-Notice Review: February 7, 2020

Automatic Refill Programs

16 CCR § 1717.5

Title 16. BOARD OF PHARMACY
Proposed Text

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.

(1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.

(2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.

(3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.

(4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.

(5) The patient or patient's agent shall have the option to withdraw from the program at any time.

(6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.

(7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.

(8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.

(9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.

(b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

Pharmacy Ownership, Management, and Control, Including Through Trusts
16 CCR § 1709

Title 16. Board of Pharmacy
Proposed Text

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. ~~Names of Owners and Pharmacist In Charge~~ Disclosure and Notification Requirements

(a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~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 and 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 ~~B~~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~~ license was issued, shall require written notification to the board within 30 days.

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership ~~transfer of permit~~ and shall require a new application for ~~a change of ownership~~ licensure:

(1) 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. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.

(d) If any beneficial interest of the pharmacy is held in trust, the applicant, licensee, or any person with management or control of the pharmacy, shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and annual renewal, report the name of any other person in any position with management or control of the pharmacy.

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the annual renewal, the name, address and contact information for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and annual renewal shall also include the name, address, and contact information for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the pharmacy.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4110, 4111, 4112, 4113, 4120, ~~4124~~, ~~4130~~, ~~4133~~, ~~4141~~, ~~4149~~, ~~4160~~, ~~4161~~, ~~4196~~, 4201, 4302, ~~4304,~~ 4305, 4307, 4308, and 4330, Business and Professions Code.

Third-Party Logistics Providers and Dangerous Drug Distributors
16 CCR §§ 1780-1783

Title 16. Board of Pharmacy

Proposed Language

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1780. Minimum Standards for Wholesalers and Third-Party Logistics Providers.
The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the standards set forth in the latest edition of 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 and ~~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 the standards set forth in the latest edition of the ~~appropriate~~ United States Pharmacopeia ~~Standards (1990, 22nd Revision)~~.

(f) Policies and procedures must be written and made available upon request by the board.

(1) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

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

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161, 4161.5 ~~and~~ 4304, and 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

To Amend Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1781. ~~Exemption Certificate~~ Pharmacist or Designated Representative on Premises and In Control.

(a) A registered pharmacist, or a 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.

(b) A designated representative – 3PL certified in accordance with Section 4053.1 of the Business and Professions Code, shall be present and in control of a third-party logistics provider's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4053, 4053.1, 4160, and 4161 ~~4054~~, Business and Professions Code.

To Amend Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1782. Reporting Sales of Drugs Subject to Abuse.

~~All~~ Each manufacturer~~s~~, ~~and~~ wholesaler~~s~~, and third-party logistics provider 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.

Note: Authority cited: Section 4005, Business and Professions Code~~; and Section 26692, Health and Safety Code~~. Reference: Sections 4053.1, 4081, 4164, 4165, and 4332, Business and Professions Code~~; and Section 26692, Health and Safety Code~~.

To Amend Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1783. Manufacturer, ~~or~~ Wholesaler, or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or~~ wholesaler, or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or~~ wholesaler, or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or~~ wholesaler, or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous

drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the p~~m~~ermit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4163, 4165 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

Self-Assessment Forms
16 CCR § 1715
17M – 13
17M – 14

Title 16. Board of Pharmacy
Proposed Regulation

Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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 use ~~The~~ the components of this assessment ~~shall be~~ on Form 17M-13 (Rev. 10/~~14~~ 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment ~~and~~ on Form 17M-14 (Rev. 10/~~14~~ 16) entitled "Hospital Pharmacy Self-Assessment." ~~which are~~ Both forms are hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations~~.

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

(A) Name and license number of the pharmacy

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

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

(D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, 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 each of the requirements 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 form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and 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.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and 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.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(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.

Self-Assessment Form
16 CCR § 1784
17M – 26

Proposal to Amend 16 CCR Amend § 1784

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

(a) ~~The designated representative-in-charge of~~ Eeach wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ 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 ~~wholesaler permit~~ license is issued, ~~or~~

(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) ~~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~~. Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) 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 and license number of the premises;

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

(C) 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) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;

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

(C) He or she understands 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 he or she has read and reviewed the completed self-assessment and understands 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 kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(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.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

Automated Drug Delivery Systems (ADDS) 16 CCR §§ 1711, 1713, and 1715.1

Title 16. Board of Pharmacy
Proposed DRAFT Regulation

Proposal to amend §1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by 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 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 an automated drug delivery system, or

(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 ##X-## (Rev 12/18) entitled "Automated Drug Delivery System Self-Assessment". Form ##X-## 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

(3) 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.

(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 in ink on the self-assessment form.

(6) 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 on the self-assessment form.

(7) 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 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.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment. An automated drug delivery system shall correct any non-compliance 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, 4119.1, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, and 4333, 4400, 4427, 4427.1, 4427.2 4427.3, 4427.4, and 4427.5 Business and Professions Code.

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 1715.1 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy License #: _____
Expiration Date: _____
DEA Registration #: _____
DEA Expiration Date: _____
DEA Inventory Date: _____
Last C2 Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____**RPH#**_____
ADDS License #: _____
ADDS Expiration Date:_____
ADDS Address: _____
City: _____
ADDS Hours: **M-F:** _____**Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, 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. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined, that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by Section 256b of Title 42 of United Sates Code. [BPC 4119.11(a)-(a)(11)]

☐☐☐ 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

☐☐☐ 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to Section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with Section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

Yes No N/A

☐☐☐ 2.4 Provides pharmacy services through **a clinic** licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in Section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- Use of the ADDS is consistent with legal requirements.
- The proposed location for installation of the ADDS met the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
- The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

☐☐☐ 3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]
List date(s) of pre-license inspection(s):

_____
_____
_____

☐☐☐ 3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

Yes No N/A

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]

☐☐☐ 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Please Note: The Pharmacist-in-Charge of the pharmacy and the owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.

- ☐ SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5 – ADDS adjacent to the secured pharmacy area and Medical Offices.
- ☐ SECTION 6 – ADDS in a health facility pursuant to HSC 1250 (LTC).
- ☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- ☐ SECTION 8 – ADDS operated by a correctional clinic.

SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 4.1 Covered Entity May Contract with Pharmacy to Provide Services- The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC Section 4126 to provide those pharmacy services through the use of the APDS. [BPC 4119.11(a)(2)]

☐☐☐ 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by the Health Resources and Services Administration and are available for inspection by Board during normal business hours. [BPC 4126(a)]

☐☐☐ 4.3 Drugs purchased and received pursuant to Section 256b of Title 42 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

Yes No N/A

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____

☐☐☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]

☐☐☐ 4.18 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. [BPC 4119.11(a)(5)]
- The operation of the APDS. [BPC 4119.11(a)(5)]
- The maintenance of the APDS. [BPC 4119.11(a)(5)]
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

☐☐☐ 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]

☐☐☐ 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]

☐☐☐ 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.21 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]

☐☐☐ 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐☐☐ 4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.27.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2)]

Yes No N/A

☐☐☐ 4.27.3 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3)]

☐☐☐ 4.27.4 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐☐☐ 4.27.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]

☐☐☐ 4.27.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐☐☐ 4.27.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐☐☐ 4.27.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

☐☐☐ 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]

☐☐☐ 4.28 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.29 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.30 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.31 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 4.35 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.37 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4105.5(c)(2)]

☐☐☐ 4.38 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA AND IN MEDICAL OFFICES.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l)]

☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]

- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
- Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 5.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]

Yes No N/A

☐☐☐ 5.7 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

Yes No N/A

☐☐☐ 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

☐☐☐ 5.15 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.16 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.17 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 5.18 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.19 The labels on all drugs and devices dispensed by the APDS comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.20 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.21 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]

☐☐☐ 5.22 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.23 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.24 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 5.25 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]

☐☐☐ 5.26 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.27 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.28 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.29 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)]

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. [HSC 1261.6 (a)(3)]

Yes No N/A

☐☐☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]

☐☐☐ 6.2 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6 (d)(1)]

☐☐☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.4 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]

☐☐☐ 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]

☐☐☐ 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]

☐☐☐ 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]

☐☐☐ 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

☐☐☐ 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS are accounted for;
- Access to ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

☐☐☐ 6.10 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.11 The stocking and restocking of the ADDS is performed in compliance with Section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1)]

☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 6.13 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.14 The information required by BPC Section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

Yes No N/A

☐☐☐ 6.15 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 drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.16 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. [HSC 1261.6(e)(2)]

☐☐☐ 6.17 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the

ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6 (f)]:

Yes No N/A

☐☐☐ 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]

☐☐☐ 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]

☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]

☐☐☐ 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7 (b)]

☐☐☐ 6.27 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.28 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.29 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.30 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.31 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]

☐☐☐ 6.33 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

☐☐☐ 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐☐☐ 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

Yes No N/A

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule ll controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule ll controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule ll controlled substances** since that last inventory reconciliation report:

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

☐☐☐ 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐☐☐ 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

☐☐☐ 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 7.14 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

Yes No N/A

☐☐☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐☐☐ 7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

Yes No N/A

☐☐☐ 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐☐☐ 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]

☐☐☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐☐☐ 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to

subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]

☐☐☐ 7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]

☐☐☐ 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]

☐☐☐ 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of Section 1206 of the Health and Safety Conde, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

Yes No N/A

☐☐☐ 8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

☐☐☐ 8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of Section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 8.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

☐☐☐ 8.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 8.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 8.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 8.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

☐☐☐ 8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]

☐☐☐ 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 8.20 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 8.21 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

☐☐☐ 8.22 The review is 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. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 8.23 Drugs removed from the ADDS is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 8.24 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 8.25 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 8.26 Drugs from the ADDS in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 8.27 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
16 CCR § 1747 (Permanent)

Title 16. Board of Pharmacy
Proposed Text

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 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 or provided by a provider accredited by an approved accreditation agency that satisfies 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 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. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

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

Attachment 4

Regulation Timelines

d. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

   Timeline:
   Approved by Board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: January 23, 2017
   Returned to the Board: March 28, 2017
   Re-submitted to DCA for Pre-Notice Review: August 21, 2017
   Returned to the Board: February 24, 2018
   Modified language approved by Board: March 27, 2018
   Re-submitted to DCA for Pre-Notice Review: July 11, 2018
   Returned to the Board: August 20, 2018
   Re-submitted to DCA for Pre-Notice Review: October 26, 2018
   Returned to the Board: December 12, 2019

2. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

   Timeline:
   Approved by Board: January 29, 2020

3. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

   Timeline:
   Approved by Board: January 29, 2020

Pharmacy Technician

16 CCR § 1793.5, 1793.6, and 1793.65

Title 16. Board of Pharmacy
Proposed Regulation Text

Proposal to amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 7/2018)), 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, and 4202, ~~4207 and 4400,~~ Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402~~ and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Proposal to amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
(~~1~~ A) Knowledge and understanding of different pharmacy practice settings.

(~~2~~ B) 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~~ C) 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~~ D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
(~~5~~ E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
(~~6~~ F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
(~~7~~ G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.
(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:
(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.
(B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.
(C) Require students to be at least 18 years of age prior to the beginning of instruction.
(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115,~~ and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:
(1) The Pharmacy Technician Certification Board, and
(2) The National Healthcareer Association.
(b) Approval of these programs is valid through December 31, 2021.

Note: Authority cited: Business and Professions Code Sections 4005 and 4202. Reference: Business and Professions Code Sections 4038 and 4202.

Attachment 6: Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

A hardcopy of the proposed pharmacy technician application will be made available at the meeting or upon request. Requests may be emailed to Debbie.Damoth@dca.ca.gov.

Drug Losses
16 CCR § 1715.6

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.

(3) Any other ~~substantial~~ significant loss as determined by the pharmacist-in-charge.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

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

Inventory Reconciliation

16 CCR § 1715.65

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.
(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.

(b) The pharmacist-in-charge of a pharmacy or ~~consultant~~ consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports ~~taken~~ prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled ~~drugs~~ substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory reconciliation reports required by this section.

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) Possible causes of overages ~~shall be identified in writing and incorporated into the inventory reconciliation report~~.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances.

(e)(1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-in-charge or professional director (if a clinic) ~~and~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report ~~as required in subdivision (c)~~ for those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory reconciliation

report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist in charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~shall ensure that:~~

~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~

~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~

~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~

~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.