California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Legislation and Regulation Committee
Chair Report

Greg Lippe, Public Member, Chair
Lavanza Butler, Licensee Member, Vice Chair
Ryan Brooks, Public Member
Shirley Kim, Public Member
Maria Serpa, Licensee Member

a. Call to Order and Establishment of Quorum

b. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

c. Discussion and Consideration of Board-Sponsored Legislation: 2019 Sunset Review Items Resulting in Possible Legislation

Attachment 1

As part of the board's Sunset Report, several legislative policies were discussed. Provided below are brief summaries of the provisions. With the exception of the ADDS, the assessment of an inspection fee for sterile compounding pharmacies, and the facility licensing cancellation proposals, the members have not previously reviewed the language that could be used to facilitate the policy change.

1. Amend Business and Professions (BPC) Code section 4427.3 and add a new section to Expand the Locations in which Automated Drug Delivery Systems (ADDS) can be Licensed

   Summary: This proposal allows to expand the locations in which ADDS can be licensed to include all facilities listed in Health and Safety Code 1250 as well as other locations licensed by the state that as a function of the underlying license are authorized to offer medication services.

   This proposal was approved for sponsorship at the November 2019 Board Meeting.

2. Amend BPC sections 4161 and 4400 to Provide an Alternative Pathway to Licensure as a Nonresident Third-Party Logistics Providers

Summary: This proposal will allow for the licensure of nonresident third-party logistics providers in a manner similar to the licensure process used for initial licensure of nonresident sterile compounding pharmacies.

3. Amend BPC sections 4127.3, 4129.4, and 4316 Relating to the Cease and Desist Appeal Hearing

   Summary: This proposal clarifies the hearing date of a cease and desist appeal to occur within five business days.

4. Amend BPC section 4343 to Expand the Prohibition Against Non Pharmacies Using any Words for Licensed Pharmacy

   Summary: This proposal would prohibit any non pharmacy website from using words like pharmacy.

5. Amend BPC section 4400 and add BPC section to Assess a Fee for an Inspection Resulting from the Remodel of a Sterile Compounding Pharmacy

   Summary: This proposal would require an assessment of a remodel inspection fee for in-state sterile compounding pharmacies and to assess the remodel inspection fee and travel costs for out-of-state sterile compounding pharmacies.

   This proposal was approved for sponsorship at the May 2019 Board Meeting.

6. Amend BPC section 4312 to Expand the Provisions for Cancellation of a Facility License

   Summary: This proposal clarifies the board may cancel the license of any new and existing facility licensed by the board.

   The proposal was approved for sponsorship at the November 2019 Board Meeting.

7. Amend BPC section 4314 to Clarify that a Citation is not Considered Disciplinary Action

   Summary: This proposal clarifies existing language that the board does not consider a citation a disciplinary action.

d. Discussion and Consideration of Board Approved Legislation for Sponsorship

Attachment 2

1. Amend BPC section 4052.11 Regarding Continuing Education Requirement for Pharmacists Prescribing Schedule II Drugs Under a Collaborative Practice Agreement

Summary: This proposal provides for pharmacists who prescribe Schedule II drugs under a Collaborative Practice Agreement to complete continuing education (CE) for prescribers on the hazards of opioid use.

The proposal was approved for sponsorship at the January 2019 Board Meeting.

2. Amend BPC section 4052 to Allow Pharmacists to Furnish Non-Opioid Medication-Assisted Treatment Pursuant to a Statewide Protocol

   Summary: This proposal would provide for the authority for a pharmacist to furnish non-opioid medication assisted treatment pursuant to a statewide protocol.

   The proposal was approved for sponsorship at the May 2019 Board Meeting.

3. Amend BPC sections 4052 and 4052.6 to Expand the Conditions for Pharmacists Operating Under a Collaborative Practice Agreement

   Summary: This proposal would expand the use of the conditions under which pharmacists could operate under a collaborative practice agreement.

   The proposal was approved for sponsorship at the May 2019 Board Meeting.

4. Amend BPC sections 4022.5, 4022.7, 4053, 4053.1, and 4053.2 to Align Requirements for Designated Representatives Requirements

   Summary: This proposal clarifies and makes consistent the definition and requirements of designated representatives.

   This proposal was approved for sponsorship at the November 2019 Board Meeting.

5. Amend BPC section 4210 to Change the Requirements to Qualify for an Advanced Practice Pharmacist License

   Summary: This proposal recasts the requirements for licensure as an advance practice pharmacist license to completion of one requirement as identified in BPC 4210(a)(2) is subsumed within completion of another requirement specified, such completion would satisfy the requirement of the law in BPC 4210(a)(2). Further, to accept if certification is earned as part of the requirements for completion of a residency or completion of 1,500 hours of collaborative practice experience or a residency is completed that included the 1,500 hours of collaborative practice experience.

   This proposal was approved for sponsorship at the November 2019 Board Meeting.

6. Amend BPC sections 4427.7 and 4119.11 regarding the frequency between ADDS and pharmacy self-assessments

   Summary: This proposal will align the ADDS self-assessment requirements with the pharmacy self-assessment requirement in Title 16 CCR 1715.

   This proposal was approved for sponsorship at the November 2019 Board Meeting.

e. Discussion and Consideration of Board Adopted Regulations Approved by the Office of Administrative Law

Attachment 3

1. Title 16 CCR Section 1749 Related to the Board's Fee Schedule

   Summary of Regulation: As approved, the board's fees are increased to address the structural imbalance within the board's budget.

   Status: This proposal was approved by OAL on November 12, 2019 and will become effective April 1, 2020. Board staff are working with the department on implementation including making necessary programing changes and updating system generated notices. Staff is also working on a communication plan to ensure licensees and applicants are aware of the upcoming changes.

f. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Office of Administrative Law

Attachment 4

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 creating the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

   Status: Formal review by OAL began on December 11, 2019. Under the provisions of the Administrative Procedures Act, the review must be completed by January 27th. An update will be provided at the Board meeting.

g. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Attachment 5

1. 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 and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

Status: Formal post-adoption review by DCA began on December 11, 2019.

2. 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: Formal post-adoption review by DCA began on December 17, 2019.

h. 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 6

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 6**.

- **Regulations under Pre-Notice review by the Business, Consumer Services and Housing Agency**

1. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Summary of Regulation: This proposal amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

Status: **Approved by DCA and Submitted to Agency for Formal Review: December 5, 2019**

2. 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

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

   Summary of Regulation: This proposal updates the renewal requirement language to include all licensing programs and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

   Status: Approved by DCA and Submitted to Agency for Formal Review: December 20, 2019

- **Regulations under Pre-Notice review by DCA Legal or DCA Budget Office**

4. 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: December 12, 2019**

5. 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

6. 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: Under review by DCA Budget Office: December 13, 2019

7. 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 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

8. 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

9. Proposed Regulations 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 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: Under review by DCA Budget Office: December 31, 2019

10. Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria

    Summary of Regulation: This proposal will increase transparency and clarity to license applicants with respect to rehabilitation criteria the board considers when evaluating an applicant's eligibility for licensure.

Status: **Submitted to DCA for Pre-Notice Review: May 31, 2019**

11. Proposed Regulations to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing

    Summary of Regulation: This proposal will require establish the criteria a pharmacy must meet to identify and ensure a person is assigned to assist the pharmacist as needed when the pharmacist is working as alone in compliance with B&P section 4113.5.

    Status: Under review by DCA Budget Office: January 16, 2020

i. Future Committee Meeting Dates

The committee will meet on the following dates:

- May 6, 2020
- July 9, 2020
- October 27, 2020

Attachment 1

Amend Business and Professions (BPC) Code section 4427.3 and add a new section to Expand the Locations in which Automated Drug Delivery Systems (ADDS) can be Licensed

Proposal to Amend Business and Professions Code Section 4427.3 to read as follows:

(a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

(6) If the ADDS is an AUDS, in a location as provided in Section 4427.65(a).

(b) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement 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. These policies…

Proposal to Add Section 4427.65 to read as follows:

(a) In addition to the locations authorized in Section 4427.3, an AUDS may also be located and operated in any of the following locations:

(1) Facility licensed by this state with the statutory authority to provide pharmaceutical services.

(2) Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.

(b) The pharmacy operating the AUDS shall develop and implement, and review annually, written policies and procedures pertaining to the device.

(c) The pharmacy shall operate the AUDS in compliance with the following requirements:

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

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

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

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

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

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

(B) 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.

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

(5) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

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

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

(C) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

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

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

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

(G) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

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

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

(B) 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.

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

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

Amend BPC sections 4161 and 4400 to Provide an Alternative Pathway to Licensure as a Nonresident Third-Party Logistics Providers

ARTICLE 11. Wholesalers, Third-Party Logistics Providers, and Manufacturers [4160 - 4169.1]
(Heading of Article 11 amended by Stats. 2014, Ch. 507, Sec. 16.)

4161.
(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. <u>The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.</u>

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the

board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Amend BPC sections 4127.3, 4129.4, and 4316 Relating to the Cease and Desist Appeal Hearing

Proposal to amend BPC section 4127.3. Cease and Desist Order; Hearing
(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c)The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

Proposal to amend BPC section 4129.4. Cease and Desist Order
(a)Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.

(c)The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

(d)Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

Proposal to amend BPC section 4316. Board Authorized to Issue Cease and Desist Orders
(a)The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure without obtaining that licensure.

(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c)The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the facility pursuant to Section 1094.5 of the Code of Civil Procedure.

Amend BPC section 4343 to Expand the Prohibition Against Non Pharmacies Using any Words for Licensed Pharmacy

Proposal to amend BPC section 4343 to read as follows:
Buildings or Websites: Prohibition Against the Use of Certain Signs Unless Licensed Pharmacy Within

No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110. Further, no website shall have within it or used in connection with it a sign bearing the words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless the website is under the control of a pharmacy holding a license issued by the board pursuant to Section 4110.

Amend BPC section 4400 and add BPC section 4127.5 to Assess a Fee for an Inspection Resulting from the Remodel of a Sterile Compounding Pharmacy.

Proposal to Amend Business and Professions Code section 4400. Fees

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

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

…

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855). <u>The fee for the inspection of a remodeled facility shall be $780 dollars.</u>

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant. <u>The fee for inspection of a remodeled facility shall be $780 dollars. In addition to paying the remodel inspection fee, the nonresident sterile compounding pharmacy shall deposit, when requested by the board following receipt of a remodel notification, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.5. If the required deposit is not submitted, the remodel notification will be deemed to be incomplete. If the actual cost of the inspection exceeds the amount</u>

deposited, the board shall provide to the applicant a written invoice for the remaining amount. Any remaining outstanding balance will be added to renewal costs.

…

Proposal to Add Business and Professions Code section 4127.5

A pharmacy licensed pursuant to 4127.1 or 4127.2 must notify the board of its intentions to remodel a facility within 30 days of initiation of the remodel. As part of the notification the licensee must provide the anticipated date of completion and the provisions for patient care during the remodel. For any remodel that results in recertification of an ISO classified area under USP 797 the board must perform an inspection to confirm compliance with this article and regulations approved by the board prior to resumption of sterile compounding within the facility. When possible, the board will conduct the inspection within the preceding 90 days of renewal of the license. In such instances a remodel inspection fee shall not be required.

Amend BPC section 4312 to Expand the Provisions for Cancellation of a Facility License

Proposal to amend BPC Section 4312 - Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock

(a) The board may cancel ~~the license of~~ a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ license of a facility which is licensed by the board if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If ~~the~~ a facility license issued by the board ~~of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility~~ is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility licensed by the board is located, authorizing the board to enter the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, “closed” means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120 day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

Amended BPC section 4314 to Clarify that a Citation is not Considered Disciplinary Action

Proposal to amend BPC section 4314. Orders of Abatement

(a)The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b)Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c)Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d)Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

<u>(e)The issuance of a letter of admonishment pursuant to subdivision (b) of section 4315 shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.</u>

Attachment 2

Amend BPC section 4052.11 Regarding Continuing Education Requirement for Pharmacists Prescribing Schedule II Drugs Under a Collaborative Practice Agreement

Business and Professions Code Section 4052.11 is added to read:

Effective [six months of the effective date of the legislation] a pharmacist who, pursuant to any authority of this article, prescribes a Schedule II controlled substance, shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs. A pharmacist who has completed such a course within the last four years shall be deemed to have satisfied this requirement.

Amend BPC section 4052 to Allow Pharmacists to Furnish Non-Opioid Medication-Assisted Treatment Pursuant to a Statewide Protocol

Furnishing to Prescriber; Permitted Procedures by Pharmacist:

(a) Notwithstanding any other law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber…
…

(14) Provide non-opioid medication-assisted treatment pursuant to a state protocol.

Amend BPC sections 4052 and 4052.6 to Expand the Conditions for Pharmacists Operating Under a Collaborative Practice Agreement

Furnishing to Prescriber; Permitted Procedures by Pharmacist:

(a) Notwithstanding any other law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber…
(13) Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

Relevant Laws

4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility:

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.
(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

4052.2. Permitted Pharmacist Procedures in Health Care Facility; Home Health Agency or Clinic with Physician Oversight:

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional center, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency,

licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.
(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.
(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:
(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.
(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.
(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.
(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.
(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:
(1) Successfully completed clinical residency training.
(2) Demonstrated clinical experience in direct patient care delivery.

4052.6. Advanced Practice Pharmacist; Permitted Procedures:

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.
(3) Refer patients to other health care providers.
(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.
(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.
(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.
(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.
(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

Proposed Amendments to the following Business and Professions Code Sections 4022.5, 4022.7, 4053, 4053.1 and 4053.2.

4022.5. Designated Representative; Designated Representative-in-Charge:

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.
(b) "Designated representative-in-charge" means a designated representative, ~~or~~ a designated representative-reverse distributor, or a pharmacist licensed in the home state proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

4022.7. Designated Representative-3PL; Responsible Manager:

(a) "Designated representative-3PL" means an individual to whom a license has been granted pursuant to Section 4053.1. A pharmacist fulfilling the duties of Section 4053.1 shall not be required to obtain a license as a designated representative-3PL.
(b) "Responsible manager" means a designated representative-3PL or a pharmacist licensed in the home state selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer:

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.
(b) An individual who is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past

three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.
(4) The board may, by regulation, require training programs to include additional material.
(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

4053.1. Designated Representative-3PL to Supervise Third-Party Logistics Provider:

(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.
(b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall meet one of the following requirements:
(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.
(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer,

performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii) Knowledge and understanding of quality control systems.
(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B) The board may, by regulation, require the training program required under this paragraph to include additional material.
(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.
(c) A third-party logistics provider shall not operate without a pharmacist or ~~at least one~~ designated representative-3PL present at each of its licensed places of business as required under Section 4160.

4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements:

(a)Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.
(b)An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall meet one of the following requirements:
(A)Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.
(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3)(A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i)Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii)Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii)Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.
(iv)Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B)The board may, by regulation, require the training program required under this paragraph to include additional material.
(C)The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.
(c)A reverse distributor shall not operate without a pharmacist, ~~at least one~~ designated representative, or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

Relevant Law

4022.6. Designated Representative-Reverse Distributor:

"Designated representative-reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

Amend BPC section 4210 to Change the Requirements to Qualify for an Advanced Practice Pharmacist License

Proposed Statutory Language – Requirements to Qualify: Advanced Practice Pharmacist:

Business and Profession Code 4210:

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:
(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.
(2)(A) Satisfy any two of the following criteria:
(~~A~~i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
(~~B~~ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
(~~C~~iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.
(B) For purposes of this subsection, if, as a condition of completion of one of the required criteria fulfillment of a second criteria is also required such completion shall be deemed to satisfy the requirements of this subsection.
(3) File an application with the board for recognition as an advanced practice pharmacist.
(4) Pay the applicable fee to the board.
(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.
(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.
(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

Amend BPC sections 4119.11 and 4427.7 Relating to Self-Assessment Form Requirements

4427.7. Self-Assessment and Recordkeeping Requirements:

(a)A pharmacy holding an ADDS license shall complete a ~~an annual~~ self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b)The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

4119.11. Automated Patient Dispensing Systems:

(a)A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1)The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.

(2)The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3)Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4)The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5)The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6)The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7)The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

(8)Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.

(9)The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10)The automated patient dispensing system license shall 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 automated patient dispensing system license may be submitted to the board.

(11)A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

(b)For purposes of this section, the following definitions shall apply:

(1)An “automated drug delivery system” (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the 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.

(2)An “automated patient dispensing system” (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3)An “automated unit dose system” (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c)(1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

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

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:

(1)The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A)Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B)Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C)Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E)Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F)Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.

(2)The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3)The automated patient dispensing system 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.

(4)A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5)Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7)The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8)The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9)Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10)The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11)The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e)Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

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

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

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

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

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

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

(i) A pharmacy holding an automated patient dispensing system license shall complete a ~~an annual~~ self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.
(Added by Stats. 2018, Ch. 647, Sec. 1. (AB 2037) Effective September 21, 2018.)

Attachment 3

Regulation Timeline

e. Discussion and Consideration of Board Adopted Regulations Approved by the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule

   Timeline:
   Approved by Board: December 14, 2018
   Submitted to DCA for Pre-Notice Review: December 17, 2018
   45-Day Comment Period began: April 26, 2019 and Closed June 10, 2019
   Adopted by Board: June 21, 2019
   Submitted to DCA for Formal Review: June 24, 2019
   Submitted to OAL for Final review: September 30, 2019
   Approved by OAL on November 12, 2019
   Effective Date: April 1, 2020

Fee Schedule
16 CCR § 1749

Title 16. Board of Pharmacy
Order of Adoption

Proposal to Amend section 1749 in Article 6 of Division 17 of Title 16 California Code of Regulations to read as follows:

1749. Fee Schedule.

The application, renewal, penalties, and other fees, unless otherwise specified, ~~for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with section 163.5 of the Business and Professions Code and Pharmacy Law~~ are hereby fixed as follows:

(a) The fee for the issuance of any pharmacy license, including a remote dispensing site pharmacy license, is ~~five hundred twenty dollars ($520)~~ five hundred seventy dollars ($570). The fee for the annual renewal of any pharmacy license, including a remote dispensing site pharmacy license, is ~~six hundred sixty five dollars ($665)~~ nine hundred and thirty dollars ($930). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of any temporary pharmacy license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license is ~~shall be one hundred and forty dollars ($140)~~ one hundred ninety-five dollars ($195). The fee for the biennial renewal of a pharmacy technician license is ~~shall be one hundred forty dollars ($140)~~ one hundred ninety-five dollars ($195). The penalty for failure to renew ~~a pharmacy technician license~~ is ~~seventy dollars ($70)~~ ninety-seven dollars and fifty cents ($97.50).

(d) The application fee for ~~application and~~ examination as a pharmacist is ~~two hundred sixty dollars ($260)~~ two hundred eighty-five dollars ($285).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is ~~one hundred ninety-five dollars ($195)~~ two hundred and fifteen dollars ($215).

(2) The application fee for ~~application of~~ an advanced practice pharmacist license is three hundred dollars ($300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist~~'s~~ license expires.

(g)(1) The fee for the biennial renewal of a pharmacist~~'s~~ license is ~~three hundred sixty dollars ($360)~~ five hundred five dollars ($505). The penalty fee for failure to renew is one hundred fifty dollars ($150).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance ~~or renewal~~ of a wholesaler or third-party logistics provider license is ~~seven hundred eighty dollars ($780)~~ eight hundred twenty dollars ($820). The fee for the annual renewal of a wholesaler or third-party logistics provider license is eight hundred twenty dollars ($820).The penalty for failure to renew is one

hundred fifty dollars ($150). The fee for a temporary wholesaler or third-party logistics provider license is seven hundred fifteen dollars ($715).

(i) The fee for the issuance of a hypodermic license is ~~one hundred seventy dollars ($170)~~ two hundred forty dollars ($240). The fee for the annual renewal of a hypodermic needle license is two hundred eighty dollars ~~($200)~~ ($280). The penalty for failure to renew is one hundred forty dollars ~~($100)~~ ($140).

(j) The fee for the issuance of a ~~license as a~~ designated representative license pursuant to Section 4053 of the Business and Professions Code, ~~or~~ a designated representative-3PL license pursuant to Section 4053.1 of the Business and Professions Code, or a designated representative-reverse distributor license pursuant to Section 4053.2 of the Business and Professions Code, is ~~one hundred fifty dollars ($150)~~ two hundred ten dollars ($210). The fee for the annual renewal of a license as a designated representative, ~~or~~ designated representative-3PL, or a designated representative-reverse distributor is ~~shall be two hundred and fifteen dollars ($215)~~ three hundred dollars ($300). The penalty for failure to renew is ~~one hundred seven dollars and fifty cents ($107.50)~~ one hundred fifty dollars ($150).

(k) The application fee for ~~the application or renewal of~~ a license as a nonresident wholesaler or nonresident third-party logistics provider is ~~seven hundred eighty dollars ($780)~~ eight hundred twenty dollars ($820). The fee for the annual renewal of a nonresident wholesaler or nonresident third-party logistics provider is eight hundred twenty dollars ($820). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a nonresident wholesaler or nonresident third-party logistics provider temporary license is seven hundred fifteen dollars ($715).

(*l*) The fee for an intern pharmacist license is ~~one hundred sixty-five dollars ($165)~~ two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).

(m) The fee for the reissuance of any ~~permit,~~ license, ~~or certificate,~~ or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred thirty dollars ~~($100)~~ ($130).

(n) The fee for the reissuance of any license that has been lost or destroyed or reissued due to a name change is forty-five dollars ($45).

(o) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(p) The fee for the issuance of a clinic license is ~~five hundred twenty dollars ($520)~~ five hundred seventy dollars ($570). The fee for the annual renewal of a clinic license is ~~three hundred twenty-five dollars ($325)~~ three hundred sixty dollars ($360). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a nongovernmental license to compound sterile drug ~~products~~ preparations or a hospital satellite compounding pharmacy license is ~~one thousand six hundred forty-five dollars ($1,645)~~ two thousand three hundred five dollars ($2,305). The fee for the annual renewal of a nongovernmental license to compound sterile drug ~~products~~preparations or a hospital satellite compounding pharmacy license is ~~one thousand three hundred twenty-five dollars ($1,325)~~ one thousand eight hundred fifty-five dollars ($1,855). The penalty for failure to renew a nongovernmental license to compound sterile drug preparations or a hospital

satellite compounding pharmacy license is one hundred fifty dollars ($150). The fee for a nongovernmental temporary license to compound sterile drug preparations or a hospital satellite compounding pharmacy temporary license is ~~five hundred fifty dollars ($550)~~ seven hundred fifteen dollars ($715).

(r) The fee for the issuance of a nonresident sterile compounding pharmacy is ~~two thousand three hundred eighty dollars ($2,380)~~ three thousand three hundred thirty-five dollars ($3,335). The fee for the annual renewal of nonresident sterile compounding pharmacy license is ~~two thousand two hundred seventy dollars ($2,270)~~ three thousand one hundred eighty dollars ($3,180). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary nonresident sterile compounding pharmacy license is ~~five hundred fifty dollars ($550)~~ seven hundred fifteen dollars ($715).

(s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer is ~~one hundred fifty dollars ($150)~~ two hundred ten dollars ($210). The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer is ~~two hundred fifteen dollars ($215)~~ three hundred dollars ($300). The penalty for failure to renew is ~~one hundred seven dollars and fifty cents ($107.50)~~ one hundred fifty dollars ($150).

(t) The fee for a veterinary food-animal drug retailer license is ~~four hundred and thirty-five dollars ($435)~~ six hundred ten dollars ($610). The application fee for the annual renewal ~~annual renewal fee~~ for a veterinary food-animal drug retailer is ~~three hundred thirty dollars ($330)~~ four hundred sixty dollars ($460). The fee for ~~the issuance of~~ a veterinary food-animal drug retailer temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred fifty dollars ($150).

(u) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

(v) The fee for the issuance of a centralized hospital packaging pharmacy license is ~~eight hundred twenty dollars ($820)~~ one thousand one hundred fifty dollars ($1,150). The fee for the annual renewal ~~fee for~~ of a centralized hospital packaging pharmacy license is ~~eight hundred five dollars ($805)~~ one thousand one hundred twenty five dollars ($1,125). The penalty for failure to renew is one hundred fifty dollars ($150).

(w) The fee for the issuance of an outsourcing facility license is ~~two thousand two hundred seventy dollars ($2,270)~~ three thousand one hundred eighty dollars ($3,180). The ~~annual renewal~~ fee for the annual renewal of an outsourcing facility is ~~one thousand three hundred twenty-five dollars ($1,325)~~ one thousand eight hundred fifty-five dollars ($1,855). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for an ~~temporary~~ outsourcing facility temporary license is seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license is ~~two thousand three hundred eighty dollars ($2,380)~~ three thousand three hundred thirty-five dollars ($3,335). The fee for the annual renewal ~~fee for~~ of a nonresident outsourcing facility is ~~two thousand two hundred seventy dollars ($2,270)~~ three thousand one hundred eighty dollars ($3,180). The penalty for failure to renew is one hundred fifty dollars

($150). The fee for a nonresident outsourcing facility temporary license is seven hundred fifteen dollars ($715).

(y) The fee for the issuance of a correctional clinic license that is not owned by the state is five hundred seventy dollars ($570). The annual renewal application fee for a correctional clinic license is three hundred sixty dollars ($360). The penalty for failure to renew is one hundred fifty dollars ($150).

(z) The application and initial license fee for operation of an EMSADDS is one hundred dollars ($100). The application fee for the annual renewal of an EMSADDS is one hundred dollars ($100). The penalty for failure to renew is thirty-five dollars ($35).

(aa) The application fee of a co-location clinic license is seven hundred fifty dollars ($750).

(ab) The application and initial license fee for a designated paramedic license is one hundred and forty dollars ($140). The application fee for the biennial renewal of a designated paramedic license is one hundred forty dollars ($140). The penalty for failure to renew a designated paramedic license is sixty-five dollars ($65).

Note: Authority cited: Sections 4005 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, 4120, 4127.1, 4127.15, 4127.2, 4128.2, 4129.1, 4129.2, 4129.8, 4130, 4160, 4161, 4180, 4180.5, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.

Attachment 4

Regulation Timeline

f. 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 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 Final Review: December 11, 2019

Naloxone Fact Sheet
16 CCR § 1746.3

BOARD OF PHARMACY

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 5

Regulation Timeline

g. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. 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

2. 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

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.

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.

Attachment 6

Regulation Timelines

h. 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

Regulations under Pre-Notice review by the Business, Consumer Services and Housing Agency

a) Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Timeline:
Approved by Board: January 24, 2017
Submitted to DCA for Pre-Notice Review: April 27, 2017
Returned to the board: January 18, 2018
Re-submitted to DCA for Pre-Notice Review: June 25, 2018
Returned to the board: July 3, 2018
Re-submitted to DCA for Pre-Notice Review: July 13, 2018
Formal DCA Pre-Notice Review began: August 20, 2018
Returned to the board: March 19, 2019
Re-submitted to DCA for Formal Pre-Notice Review: April 9, 2019
Approved by DCA and Submitted to Agency for Formal Review: December 5, 2019

b) 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
Formal DCA Pre-Notice Review began: December 5, 2018
Approved by DCA and Submitted to Agency for Formal Review: January 9, 2020

c) Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

Timeline:
Approved by Board: May 2, 2018
Submitted to DCA for Pre-Notice Review: July 12, 2018
Returned to the board: September 6, 2018
Re-submitted to DCA for Pre-Notice Review: September 18, 2018
Returned to the board: September 28, 2018
Re-submitted to DCA for Pre-Notice Review: October 4, 2018

Formal DCA Pre-Notice Review began: October 16, 2018
Returned to the board on: July 23, 2019
Re-submitted to DCA for Pre-Notice Review: December 6, 2019
Approved by DCA and Submitted to Agency for Formal Review: December 20, 2019

Regulations under Pre-Notice review by DCA Legal or DCA Budget Office

d) 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

e) 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 3, 2020
Re-submitted to DCA for Pre-Notice Review: January 14, 2020

f) 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
Under review by DCA Budget Office: December 13, 2019

g) 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

h) 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

i) 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
Under review by DCA Budget Office: December 31, 2019

j) Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria

Timeline:
Approved by Board: May 6, 2019
Submitted to DCA for Pre-Notice Review: May 31, 2019

k) Proposed Regulations to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing

Timeline:
Approved by Board: July 25, 2019
Submitted to DCA for Pre-Notice Review: August 26, 2019
Submitted to DCA Budget Office: December 19, 2019
Returned to Board:
Re-submitted to DCA Budget Office: January 16, 2020

Offsite Storage
16 CCR § 1707

Title 16. Board of Pharmacy
Proposed Text

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1707. Waiver Requirements for Off-Site Storage of Records

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

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

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

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

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

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

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

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

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

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

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

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

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.

Renewal Requirements 16 CCR §§ 1702, 1702.1, 1702.2, 1702.5

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 1702 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements.

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.
  (1) A pharmacist ~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.
  (2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
  (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
  (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with any continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.2.

(e) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend section 1702.1 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.1. ~~Pharmacy Technician~~ Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual other than a license as a pharmacist or an advanced practice pharmacist.

(a) An individual licensee ~~pharmacy technician~~ applying ~~icant~~ for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.

(1) The individual ~~A pharmacy technician~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) The individual ~~A pharmacy technician~~ applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4038, 4115, 4202, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Repeal section 1702.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations.

~~1702.2. Designated Representative Renewal Requirements.~~

~~(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.~~

~~(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.~~

~~(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).~~

~~(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).~~

~~(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).~~

~~(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.~~

~~(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.~~

~~(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.~~

~~Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.~~

Amend section 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Renewal Requirements for Premises or Facilities ~~Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy~~.

This section applies to a renewal application submitted by a licensed premises or facility.

(a) As a condition of renewal, an applicant seeking renewal of a premises or facility license ~~as a nonresident wholesaler or as a nonresident pharmacy~~ shall report to the board any disciplinary action taken by any government agency since the issuance or last renewal of the license. ~~An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license.~~ Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation, or public reprimand or reproval.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.

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.

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

§ 17##. 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_____

_____
_____
_____
_____
_____
_____
_____

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 _____

Criminal Conviction Substantial Relationship and Rehabilitation Criteria 16 CCR §§ 1769 and 1770

Title 16. Board of Pharmacy
Proposed Regulation

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

Amend section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code on the grounds that the applicant was convicted of a crime, the board shall consider whether the applicant made a showing of rehabilitation and is presently eligible for a license, if the applicant completed the criminal sentence at issue without a violation of parole or probation. In making this determination, the board shall consider the following criteria:~~, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:~~

(1) The nature and gravity of the crime(s).

(2) The length(s) of the applicable parole or probation period(s).

(3) The extent to which the applicable parole or probation period was shortened or lengthened, and the reason(s) the period was modified.

(4) The terms or conditions of parole or probation and the extent to which they bear on the applicant's rehabilitation.

(5) The extent to which the terms or conditions of parole or probation were modified, and the reason(s) for modification.

(c) If subdivision (b) is inapplicable, or the board determines that the applicant did not make the showing of rehabilitation based on the criteria in subdivision (b), the board shall apply the following criteria in evaluating an applicant's rehabilitation. The board shall find that the

applicant made a showing of rehabilitation and is presently eligible for a license if, after considering the following criteria, the board finds that the applicant is rehabilitated:

(1) The nature and severity of the act(s) or ~~offense(s)~~crimes(s) under consideration as grounds for denial.

(2) Evidence of any act(s) or crime(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) The criteria in subdivision (b)(1)-(5), as applicable.

~~(5)~~(6) Evidence, if any, of rehabilitation submitted by the applicant.

~~(c)~~(d) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Sections 482 and 4005, Business and Professions Code. Reference: Sections 480, 481, 482, 488, 493, 4030, 4200 and 4400, Business and Professions Code.

Amend section 1770 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Section 141 or Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime, professional misconduct, or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by ~~his~~the license or registration in a manner consistent with the public health, safety, or welfare.

(b) In making the substantial relationship determination required under subdivision (a) for a crime, the board shall consider the following criteria:

(1) The nature and gravity of the offense;

(2) The number of years elapsed since the date of the offense; and

(3) The nature and duties of the profession or occupation the person may perform with the license type sought or held.

(c) For purposes of subdivision (a), substantially related crimes, professional misconduct, or acts shall include, but are not limited to, those which:

(1) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, governing the practice of pharmacy.

(2) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of any law of this state, or any other jurisdiction, relating to controlled substances or dangerous drugs.

(3) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, relating to government provided or government supported healthcare.

(4) Involve dishonesty, fraud, deceit, or corruption related to money, items, documents, or personal information.

(5) Involve a conviction for driving under the influence of drugs or alcohol.

Note: Authority cited: Sections 481, 493, and 4005, Business and Professions Code. Reference: Sections 141, 480, 481, 490, 493, 4300, 4301, 4301.5, and 4309, Business and Professions Code.

Community Pharmacy Staffing
16 CCR § 1714.3

Title 16. Board of Pharmacy
Proposed Regulation

Add section 1714.3 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

(a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee, the pharmacy must make another person available to assist a pharmacist. The pharmacy must:

(1) Designate the names of one or more persons who will be available to assist the pharmacist;

(2) Determine that each designated person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3;

(3) Determine that each designated person qualifies to access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;

(4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.

(b) A pharmacy must have and maintain policies and procedures that addresses the following:

(1) The required criteria and training for a designated person, which shall be consistent with subdivison (a).

(2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.

(3) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section.

(c) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4007, 4029, 4036, 4037, 4056, 4110, and 4113.5, Business and Professions Code.

Pharmaceutical Compounding of Nonsterile Preparations
16 CCR §§ 1735 et seq.

Title 16. Board of Pharmacy

Proposed Regulation

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

Repeal section 1735 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations and replace as follows:

~~**Article 4.5 Compounding**~~

~~**1735. Compounding in Licensed Pharmacies**~~

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

(1) ~~Altering the dosage form or delivery system of a drug~~

~~(2) Altering the strength of a drug~~

~~(3) Combining components or active ingredients~~

~~(4) Preparing a compounded drug preparation from chemicals or bulk drug substances~~

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

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

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

~~**1735.1. Compounding Definitions**~~

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

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

~~(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-~~

~~filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building exhausting. This external exhaust should be dedicated to one BSC or CACI.~~

~~d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.~~

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

~~1) For nonhazardous compounding a positive pressure differential of 0.02-to 0.05-inch water column relative to all adjacent spaces is required.~~
~~2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the

~~resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.~~

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

~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not (x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.~~

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

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

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

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

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

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

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

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

~~(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).~~
~~(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).~~
~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug preparation Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

~~1735.2. Compounding Limitations and Requirements; Self-Assessment~~

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

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

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

~~(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and~~
~~(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and~~
~~(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the~~

prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

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

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

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

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

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

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

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

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

(1) Active ingredients to be used.

(2) Equipment to be used.

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

(4) Inactive ingredients to be used.

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

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

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

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

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

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated

~~on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.~~

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

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

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

~~(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,~~
~~(B) the chemical stability of any one ingredient in the compounded drug preparation;~~
~~(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,~~
~~(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,~~
~~(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and~~
~~(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.~~
~~(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:~~

~~(i) the nature of the drug and its degradation mechanism,~~
~~(ii) the dosage form and its components,~~
~~(iii) the potential for microbial proliferation in the preparation,~~
~~(iv) the container in which it is packaged,~~
~~(v) the expected storage conditions, and~~
~~(vi) the intended duration of therapy.~~

~~Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.~~
~~(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:~~

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

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

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

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

~~(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:~~

~~(A) Method Suitability Test,~~

~~(B) Container Closure Integrity Test, and~~

~~(C) Stability Studies~~

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

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

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

~~(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.~~

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

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

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

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

1735.3. Recordkeeping of Compounded Drug Preparations

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

(1) The master formula document.

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

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

(B) The date the drug preparation was compounded.

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

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

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

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

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

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

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

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

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

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

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

purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

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

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

1735.4. Labeling of Compounded Drug Preparations

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

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);
2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;
(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
(4) The beyond use date for the drug preparation;
(5) The date compounded; and
6) The lot number or pharmacy reference number.

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

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

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

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

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

~~1735.5. Compounding Policies and Procedures~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127, and 4301, Business and Professions Code~~

~~1735.6. Compounding Facilities and Equipment~~

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

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

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

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

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

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

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

~~(3) A) For sterile compounding, each BSC or CACI shall also be externally exhausted. y~~

~~(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant HEPA filter in series or be externally exhausted.; For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.~~

~~Each PEC in the room shall also be externally vented; and~~

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

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

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

~~1735.7. Training of Compounding Staff~~

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

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

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

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

~~1735.8. Compounding Quality Assurance~~

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

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

~~(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.~~

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

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

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

1735. Nonsterile Compounding in Licensed Pharmacies

This article applies to nonsterile compounding performed in a pharmacy. A pharmacy performing nonsterile compounding shall comply with the standards established by United States Pharmacopeia (USP) General Chapter 795 (Chapter 795), titled *Pharmaceutical Compounding – Nonsterile Preparations*, unless additional or different standards are established by this article.

(a) For purposes of this article, compounding occurs in a pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription.

(b) Repackaging of a compounded nonsterile preparation (CNSP) shall be considered compounding and this article shall apply.

(c) Reconstitution in accordance with directions that have not been Food and Drug Administration (FDA) approved is considered compounding and this article applies.

(d) Consistent with the provisions of 503A of the Federal Food, Drug and Cosmetic Act, no compounded nonsterile preparations (CNSPs) shall be compounded prior to receipt by a pharmacy for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescriber, on the prescription that a compounded preparation is necessary for the identified patient.

(1) Notwithstanding subdivision (d), a pharmacy may prepare and store a limited quantity of CNSP in advance of receipt of a patient specific prescription document where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(e) No pharmacy or pharmacist shall compound a CNSP that:

(1) Is classified by the FDA as demonstrably difficult to compound;
(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drug preparations have been found to be unsafe or not effective; or
3) Is a copy or essentially a copy of one or more commercially available drug products, unless

(A) the drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, or (B) the compounding of that CNSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of

the shortage or the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(4) Is made with any component not intended for use in a CNSP for the intended patient population.

(f) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment as required by section 1715

(g) In addition to section 1707.2 of the board's regulations, consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of a CNSP and CNSP related supplies furnished by the pharmacy.

(h) Compounding with blood or blood components shall be done in compliance with Health and Safety Code section 1602.5.

(i) Storing, weighing, measuring, compounding, and/or preforming other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, [Hazardous Drugs – Handling in Healthcare Settings], and any board regulations.

(j) Storing, weighing, measuring, compounding, and/or preforming other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, [Hazardous Drugs – [Handling in Healthcare Settings], and any board regulations.

1735.1. INTRODUCTION AND SCOPE AND COMPOUNDING DEFINITIONS.

The definitions in this section supplement the definitions provided in USP Chapter 795.

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling that contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

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

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as water or sterile water for injection.

(d) “Integrity” means retention of potency until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.

(e) “Repackaging” means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation, when the act is not done pursuant to a prescription.

(f) “Preparation” means a drug or nutrient compounded in a pharmacy, which may or may not be sterile.

(g) “Product” means a commercially or conventionally manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

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

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

(j) “Potency” means an active ingredient strength.

1735.2 PERSONNEL TRAINING AND EVALUATION

The requirements of this section apply in addition to the requirements in USP Chapter 795.

(a) Training, evaluation, and requalification procedures for personnel preparing, verifying, and/or handling a CNSP shall also address the following topics:

(1) Quality assurance and quality control procedures,
(2) Container closure and equipment selection, and
(3) Component selection and handling.

(b) A pharmacist responsible for or directly supervising compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of a CNSP.

(c) Personnel who fails any aspect of training or demonstrated competency, shall not be involved in the compounding process until after successfully passing reevaluations in the deficient area(s) as detailed in the SOPs.

(d) The pharmacy must document that any person assigned to provide training has obtained training and demonstrated competency in any subject in which the person will provide training or observe and measure competency.

1735.3 PERSONAL HYGIENE AND GARBING

This section supplements the requirements established by USP Chapter 795.

(a) The supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions to determine if such condition could contaminate a CNSP or the environment. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) Prior to entry into the compounding area all hand, wrist, and other exposed jewelry or piercing shall be removed.

(c) A gown and face mask shall be used whenever a closed system processing device is required.

(d) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

(e) Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.

(f) Eye glasses shall be cleaned as part of hand hygiene and garbing, the standards for which the pharmacy shall specify in its standard operating procedures (SOPs).

(g) Before any hand hygiene or garbing accommodation is granted pursuant to USP 795 Section 3.1, the designated person shall determine that the quality of the environment and any CNSPs is not affected. Documentation of the determination shall be done prior to the accommodation being allowed.

1735.4 BUILDING AND FACILITIES

This section supplements the requirements established by USP Chapter 795.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) Compounding personnel must monitor temperatures in storage area(s) and compounding areas to determine whether the temperature remains within the appropriate range for the CNSPs or components. Monitoring shall be done either (1) manually at least once daily on days that the facility is open or (2) by a continuous temperature recording device. This shall be documented.

(c) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.

(d) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in USP Chapter 795 or the pharmacy's written SOPs

1735.5 CLEANING AND SANITIZING

This section supplements the requirements established by USP Chapter 795.

(a) Documentation of the cleaning and sanitizing of the compounding area shall reflect the name of the person completing the cleaning and sanitizing as well as the cleaning and sanitizing agents used.

(b) Any cleaning or sanitizing agents shall be used in accordance with manufacturers' specifications.

1735.6 EQUIPMENT AND COMPONENTS

This section supplements the requirements established by USP Chapter 795.

(a) Any equipment used to compound CNSP shall be used in accordance with the manufacturer's specifications.

(b) Any component used to compound a CNSP shall be used and stored, , in accordance with all industry standards including the following:

(1) United States Pharmacopeia (USP) - National Formulary (NF),

(2) Food Drug and Cosmetic Act (FD&CA) and federal regulations adopted to implement that act,

3) Food Drug Administration (FDA) requirements and considering issued Guidance Documents and Alerts, and

(4) Manufacturers' specifications and requirements.

(c) Any active pharmaceutical ingredient (API) or added substance used to compound a CNSP shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum in English and should all the requirements of USP Chapter 1080, Bulk Pharmaceutical Excipient- Certificate of Analysis. All COAs shall be readily retrievable for at least 3 years from last use in CNSP.

1735.7. MASTER FORMULATION AND COMPOUNDING RECORDS

This section supplements the requirements established by USP Chapter 795.

(a) A CNSP shall not be compounded until the pharmacy has first prepared a written master formulation document in compliance with USP Chapter 795 and identified in that document the following additional elements:

(1) Active pharmaceutical ingredient (API) or added substance(s) and their amounts, which shall include, at a minimum, salt form and purity grade, when available,
(2) Container–closure systems to be used, which shall include, container and closure types.
(3) The source referenced to assign the BUD; each source referenced shall be readily retrievable the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.
(4) Instructions for storage and handling of the compounded drug preparation.

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 795 and this section.

(c) A compounding record shall be a single document. The document shall satisfy the requirements of USP Chapters 795, as well as the following:

(1) The date and time of preparation. The time of preparation is the time when compounding the CNSP started, which also determines when the assigned BUD starts.
(2) The assigned internal identification number shall be unique for each compounded drug preparation.
(3) The total quantity compounded shall include the number of units made and volume or weight of each unit.
(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation.

1735.8 RELEASE INSPECTIONS

This section supplements the requirements established by USP Chapter 795.

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

1735.9 LABELING

This section supplements the requirements established by USP Chapter 795.

(a) A CNSP shall also include the following:
(1) Route of intended administration, and
(2) Name of compounding pharmacy and dispensing pharmacy (if different).

(b) Labeling shall also include:
(1) Any special handling instructions,

(2) Any applicable warning statements, and
(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

1735.10 ESTABLISHING BEYOND-USE DATES

This section supplements the requirements established by USP Chapter 795.

(a) Beyond use dates (BUDs) assigned with only a date shall expire at midnight at the end of date.

(b) A CNSPs BUDs shall not exceed:
(1) The chemical and physical stability data of the API and any added substances in the preparation,
(2) The compatibility of the container–closure system with the finished preparation (e.g. possible leaching, interactions, and storage conditions), or
(43) Shortest remaining expiration date or BUD of any of the starting components.

(c) (1) If the BUD of the CNSP is extended beyond the BUDs in USP Chapter 795, an aqueous CNSP, as defined by USP Chapter 795, shall be tested in compliance with USP Chapter 51, Antimicrobial Effectiveness Testing.
(2) If a pharmacy chooses to use antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature sources the full reference, including the raw data and testing method suitability, and shall be fully available at the time of compounding and three years from each dispense.

1735.11 Standard Operating Procedures (SOPs)

This section supplements the requirements established by USP Chapter 795.

(a) Standard operating procedures (SOPs) shall:
(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding,
(2) In addition to the SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, include:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.
(B) Procedures for handling, compounding, and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.
(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins

(b) Any pharmacy engaged in compounding nonsterile drug preparations shall maintain and follow written SOPs for compounding.

(c) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes are implemented. Such changes shall be disseminated to the affected staff prior to implementation.

1735.12 QUALITY ASSURANCE AND QUALITY CONTROL

This section supplements the requirements established by USP Chapter 795.

(a) The quality assurance program shall comply with section 1711 and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following:

(1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, potency, quality, or labeled strength.
(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.
(3) A written procedure addressing each of the USP Chapter 1163's integrated components and standard operating procedures.

1735.13 PACKAGING AND TRANSPORTING

This section supplements the requirements established by USP Chapter 795.

(a) There shall be a defined process and documented procedure to ensure temperature sensitive products will arrive at their desired destinations after transporting within the expected quality standards for integrity, potency, quality and labeled strength.

(b) Packaging materials shall protect CNSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transportation personnel.

(c) A pharmacist supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

1735.14 COMPLAINT HANDLING AND ADVERSE EVENT REPORTING

This section supplements the requirements established by USP Chapter 795.

(a) The pharmacy shall process recalls and adverse event reporting in compliance with Business and Professions Code section 4126.9.

(b) All complaints related to a potential quality problem with a compounded drug preparation and all adverse events shall be reviewed by the pharmacist-in-charge. Such review shall be documented and dated.

1735.15 DOCUMENTATION

This section supplements the requirements established by USP Chapter 795.

(a) Pharmacies shall maintain each record required by USP Chapter 795 or this article in the pharmacy, in a readily retrievable form, for at least three years from the date the record was last used. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records created shall be maintained in a manner to allow for all versions of the document to be viewed. When a change to a record must be made, the record's original text must be maintained, and the record must reflect each change, the person who made the change, and the date and time the change was made.

Note: Authority cited: Sections 4001.1, 4005, , 4057, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4127, 4127.7 and 4169, 4301 and 4332 of the Business and Profession Code.