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

Enforcement and Compounding Committee Report

Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chair
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member, President
Nicole Thibeau, Licensee Member

I. Presentation by the National Association of State Boards of Pharmacy on Drug Shortages Including Discussion on the National Landscape

Background
As part of the December 13, 2023 Board meeting, the Board received a request for the Board to schedule a discussion on drug shortages. The matter was referred to the Enforcement and Compounding Committee for discussion.

Summary of Committee Discussion
During the meeting members received a presentation from Andrew Funk, PharmD, NABP Director of Government Affairs and Member Relations. Dr. Funk discussed some of the market challenges that contribute to drug shortages, including access to APIs where manufacturers limit the supply. Dr. Funk noted some root causes of drug shortages including 1) lack of incentives for manufacturers to produce less profitable drugs; 2) the market does not recognize or reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues; and 3) logistical and regulatory challenges that make it difficult for the market to recover from a disruption. Dr. Funk advised the Committee of a hearing being held by the federal House Committee on Oversight and Accountability on April 11, 2024, that would, among other things, examine the FDA's response to drug shortages.

Dr. Funk also spoke specifically about stimulant shortages. In addition to discussing factors that contribute to stimulant shortages, Dr. Funk noted that sometimes the shortage is limited to generic drugs, with branded drugs continuing to be available, noting however that brand name medications may not be available to the patient because of reimbursement and coverage issues. Dr. Funk further noted that some in the supply chain capitalize on the drug shortage challenges within the market, including wholesalers that are secondary wholesalers obtaining products on short supply from pharmacies for redistribution. Dr. Funk added that implementation of track and trace requirements should provide more transparency into this business model.

Members discussed their experiences with drug shortages, including seemingly random shortages of noncontrolled oral medications, questioning if market forces could help to expand capacity. Members also noted that the issue of drug shortages is complex with no singular solution, and expressed concerns about the impact of drug shortages on specific populations including pediatric patients. Members also expressed concerns about narratives being promoted by drug manufacturers that appear to place blame for shortages on pharmacies. Dr. Funk advised members that NABP is considering looking more specifically at the issue of drug shortages and may work with the FDA to develop solutions, noting that additional work needs to be done to address the issue.

Public comment suggested that nationwide settlements between the government and large wholesalers and pharmacies have contributed to drug shortages of opioids and other pain medications, and that the Board should engage with the DEA on these shortages. Public comment also suggested that the FDA should align its assessment of drug shortages with the criteria used by ASHP, which places a focus on the impact to patients. Public comment encouraged the Board to take action where it can to address the issue of drug shortages and the impact on patients.

Attachment 1 includes a copy of the presentation slides.

II. Proposed Changes to ADDS Self-Assessment Rulemaking and Form, as Requested by the Office of Administrative Law

Relevant Law

California Code of Regulations, title 16, section 1715.1 establishes the requirement for the pharmacist-in-charge (PIC) of each automated drug delivery system (ADDS) to 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.

Background

The self-assessment form aids licensees in assessing their compliance with federal requirements, state laws, and state regulations, as well as identifying any areas in which they are noncompliant. This awareness can increase self-correction and make the facility site inspection process more meaningful. Periodic review and accountability will result in increased consumer safety and improve facility operations with respect to employee safety and the state's environment.

As the PIC is the person responsible for completing the self-assessment form, this requirement helps to educate the PIC and ensure that the PIC has knowledge of all applicable laws and regulations. In turn, this helps to ensure that pharmacies operating ADDS are following standard practices, thus protecting the safety and quality of pharmaceutical medications. The self-assessment form is being updated to reference current law and regulations and does not impose new laws. PICs are already obligated to comply with pharmacy laws and regulations; the self-assessment form is simply a tool provided by the Board to aid them in doing so.

In January 2022, the Board voted to update the self-assessment form incorporated by reference in California Code of Regulations, title 16, section 1715.1. The Board initiated the formal rulemaking process which included a 45-day comment period followed by two separate 15-day comment periods seeking additional changes to the self-assessment form. The Board adopted the regulation and self-assessment form incorporated by reference. On December 5, 2023, the final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review. Following review, edits were identified as necessary to ensure compliance with the clarity and consistency requirements of the Administrative Procedure Act (APA). As a result, the rulemaking was withdrawn from the OAL.

Summary of Committee Discussion and Action

The Committee noted that to remedy the issues identified by the OAL, the Board must again initiate the rulemaking process to update the self-assessment form incorporated by reference in section 1715.1. To ensure compliance with the APA and address the clarity and consistency issues, the language within the self-assessment form has been amended to:

- Make technical updates (*e.g.*, revision dates, formatting edits, removal of outdated language, renumbering, updating references, clarifying language).
- Align language with the statutory language more closely. Previously, the statutory requirements were paraphrased throughout the self-assessment form, which may have inadvertently altered the requirements. For example, in Section 2.9.6, in restating the provision, the phrase "during the period when pharmacy services outside the hospital are not readily available or accessible" was omitted within the self-assessment form.
- Finally, to ensure clarity within the requirements, in place of larger paragraphs, some statutory provisions have been split into smaller separately numbered subsections.

During the meeting members reviewed the proposed changes. Members noted agreement with the proposed changes and inquired about the removal of the reference to "Long-Term Care Facilities" in the title of Section 6 and requested if possible, that language be restored. It was noted that HSC 1250 referenced in this section covers several facility types.

Public comment requested that the Board release the memo from the Office of Administrative Law detailing out the requested changes. In response members and members of the public were advised that the memo can be released.

> **Committee Recommendation**: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1715.1 consistent with the Committee's discussion and self-assessment form 17M-112, incorporated by reference. Authorize the executive officer to further refine the language consistent with the Committee's discussion and OAL's recommendations and to

make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

Attachment 2 includes a copy of the previously approved amendments to 16 CCR section 1715.1, the updated ADDS self-assessment form, and comments from the Office of Administrative Law.

III. Compounding Activities by IV Hydration Clinics

Relevant Law

Section 503A of the federal Food, Drug, and Cosmetic Act (FD&C Act) describes the conditions under which compounded human drug products are exempt from the following three sections of the FD&C Act:

1. Section 505 concerning the new drug approval process;
2. Section 501(a)(2)(B) concerning compliance with current good manufacturing practice requirements; and
3. Section 502(f)(1) concerning the labeling of drugs with adequate directions for use.

Background

In recent years, the U.S. Food and Drug Administration (FDA) has released warnings about instances of drug products being compounded under insanitary conditions. Many of these warnings stem from compounding occurring in sites that are not regulated by the Board or other regulatory agencies, including IV hydration clinics. Although business models vary, such clinics have been identified as operating in a variety of locations, including mobile vans, beauty salons, and gymnasiums. These locations generally do not have the appropriate equipment, storage, or classified areas, nor do they have authorized healthcare professionals performing the sterile compounding. Board staff are frequently contacted by various agencies to assist in assessing compounding operations and practices at such facilities by providing subject matter expertise, but the Board generally lacks jurisdiction over the practice and is unable to provide meaningful consumer protection.

The FDA warnings include an example of an investigation initiated after a California patient was hospitalized and treated for suspected septic shock with multi-organ failure, after having received an IV vitamin infusion in her home. The FDA reported that it is aware of sterile compounding activities, such as adding vitamins to IV infusion bags, being performed by businesses, such as IV hydration clinics, that are not licensed by the Board of Pharmacy, the California Department of Public Health, or any other similar agency and notes that it is unknown and undocumented if the drug products are prepared, packed, or held under insanitary conditions by such entities. Additionally, it is unknown whether a licensed practitioner is on site to evaluate patients and write prescriptions for the drug products being administered. The FDA further notes that the number of these entities and the compounding practices occurring at these entities are

not fully understood given that compounders who compound drugs under section 503A of the FD&C Act generally do not register with the FDA.

Board staff have assisted in and observed inspections at some of these IV hydration clinics and have witnessed alarming practices placing consumers at risk. Staff report challenges conducting investigations because basic patient information and administration information is not adequately, or sometimes at all, recorded or maintained at many of these locations. Staff believe some of the products found in these clinics are provided to the clinics by unlicensed sources, and even where the products are coming from licensed sterile compounding pharmacies, it is suspected that many times the products are not provided consistent with the requirements of section 503A and Board regulations. An internet search of "IV Hydration Clinics in California" reveals that such businesses are extremely prevalent in our state.

Summary of Committee Discussion
During the meeting members considered several policy questions. Below is a summary of the Committee's discussion for the questions considered.

1. Does the Committee believe the Board should have a role in the regulation of IV hydration clinics?
   Committee Discussion: Members noted that the Board has the expertise to provide oversight of these practices but expressed concern with the potential impact on Board personnel. Members also noted concern for public safety stemming from potentially unsafe practices that occur at some of these clinics and noted the need to provide education to consumers and policymakers about the patient safety risks including as part of the Board's upcoming sunset report.
2. The Board currently has authority to issue a cease and desist whenever the Board has a reasonable belief, based on information obtained during an inspection or investigation, that a pharmacy compounding sterile drug products possesses an immediate threat to the public health or safety (see Business and Professions Code (BPC) section 4127.3). Does the Committee believe the Board should explore expanding its cease and desist authority to other facilities such as IV hydration clinics?
   Committee Discussion: Members noted the Board's mandate and the need to protect consumers. Members determined that the Board should work to secure authority to issue a cease and desist order where conditions in an IV hydration clinic present an immediate threat to public health, noting that without such authority there is no means to protect the public.
3. Does the Committee believe that the Board should exercise its authority to issue a cease and desist order for unlicensed practice consistent with its existing authority under BPC section 4316?
   Committee Discussion: Members agreed that the Board should use this cease and

desist authority on a case by case basis, since only after evaluating the operations, management, and control of these clinics can such a determination of unlicensed activity be made. Members cautioned that some patients have medical conditions for which IV hydration is a necessary treatment and the Board must move cautiously to ensure a barrier to care for these patients is not created.

4. The Board currently does not have authority to request records from these facilities to investigate the source of the drug products. Does the Committee believe that the Board should explore securing authority to receive such records?
   Committee Discussion: Members agreed that the Board should have such authority to request records and expressed concern about the sources of drugs being used at some of these clinics.
5. Does the Committee believe that changes to the Board's law may be necessary to require that pharmacies and wholesalers selling supplies, ingredients, or products to businesses such as IV hydration clinics must exercise due diligence prior to selling to such businesses?
   Committee Discussion: Members noted agreement that education is necessary and should be the primary focus at this time. It was noted that pharmacies and wholesalers need to ensure they have an understanding of the individuals and businesses they are selling to, but that the Board should provide education on how to vet and approve potential buyers to assure nonauthorized buyers do not have access to prescription drugs and supplies.y. It was suggested that the Board's expectation should be included as part of the educational information prepared by the Board.
6. Does the Committee believe the Board should release a policy statement encouraging compliance with federal law and compliance with USP?
   Committee Discussion: Members agreed that a policy statement is appropriate. A draft policy statement will be considered by the Committee during its July meeting.
7. Does the Committee believe the Board should release a policy statement to the public warning of the dangers of receiving intravenous products and preparations from unlicensed facilities or personnel?
   Committee Discussion: Members agreed that the Board should develop consumer-facing education providing warnings on the potential dangers of receiving IV products from unlicensed facilities or personnel. Members noted that the education should include steps a patient could take to identify appropriate sources for obtaining IV hydration treatment while also detailing the harm that has occurred in some facilities. The consumer-facing education should also include general information about the standards that must be followed to ensure the patient receives a safe product. It was suggested that development of educational information should be coordinated by the Communication and Public Education

Committee.

Public commenters suggested that the Board be mindful of how its actions related to IV hydration clinics could impact other areas of practice such as cancer infusion centers. Public comment also emphasized that to lawfully provide IV hydration a legitimate patient-prescriber relationship is required. Comments also suggested that the Board should inspection these locations.

The Committee will resume discussion on this issue during its July 2024 meeting.

IV. Updates to Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Background
Assembly Bill 1286 included several significant patient safety elements. As part of the Committee's prior discussion on implementation of Assembly Bill 1286, members requested that staff prepare a list of Frequently Asked Questions (FAQs) that the Board could release to assist stakeholders in gaining an understanding of the requirements of the measure. The FAQs were approved by the Board during its February 2024 meeting. As part of the Board's discussion, members requested that additional questions be added to the FAQs.

Summary of Committee Discussion and Action
During the meeting members reviewed the additional FAQs and noted agreement with the proposed updates. The Committee did not receive any public comment on this agenda item. The Committee is offering the following motion.

> **Committee Recommendation**: Recommend approval of the additional FAQs related to Assembly Bill 1286.

Attachment 3 includes a copy of the draft FAQs.

V. Enforcement Statistics

During the first nine months of the fiscal year, the Board received 2,453 complaints and closed 2,174 investigations. The Board has issued 138 Letters of Admonishment and 563 Citations and has referred 205 cases to the Office of the Attorney General. The Board has revoked 60 licenses, accepted the disciplinary surrender of 21 licenses, formally denied three applications, and imposed other levels of discipline against 71 licensees and/or applicants.

As of April 1, 2024, the Board had 1,566 field investigations pending. Below is a

breakdown providing more detail in the various investigation processes:

	Apr. 1, 2023		Jul. 1, 2023		Oct. 1, 2023		Jan. 1, 2024		Apr. 1, 2024	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	116	6	59	8	88	22	152	15	64	8
Cases Under Investigation	874	138	942	141	982	138	1037	146	1071	130
Pending Supervisor Review	146	22	164	31	183	47	286	77	261	62
Pending Second Level Review	245	36	79	22	82	22	81	21	141	17
Awaiting Final Closure	8	43	148	12	34	13	26	19	29	7

The Committee did not receive any comments from the public on this topic.

Attachment 4 includes the enforcement statistics for the first nine months of the fiscal year.

Attachment 1

NABP
National Association of Boards of Pharmacy

Prescription Drug Shortages

Andrew Funk, PharmD, Member Relations/Government Affairs Director

NABP Mission, Vision, and Purpose

NABP Mission Statement

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial Association that assists its member boards in protecting the public health.

Vision Statement

Innovating and collaborating today for a safer public health tomorrow.

NABP Purpose

Founded in 1904, the purpose of the Association is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensure, and practice by cooperating with state, national, and international governmental agencies and associations having similar objectives.

Member Boards

NABP's member boards of pharmacy are grouped into eight districts that include all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, and 10 Canadian provinces. The Association is governed by its Executive Committee, whose officers and members are elected during the Association's Annual Meeting.

Current Active Members: All 50 states, District of Columbia, Guam, Puerto Rico, and the Virgin Islands

Current Associate Members: Bahamas and all 10 Canadian provinces

Active vs Associate Members

Active Members

- Participate in Electronic Licensure Transfer Program® (eLTP) and NABP Clearinghouse
- Serve on NABP standing committees
- May propose resolutions and amendments to the *NABP Constitution and Bylaws*
- Privilege of the floor at the Annual Meeting
- Vote at the Annual Meeting
- Eligible to serve on NABP Executive Committee

Associate Members

- Not required to participate in eLTP or Clearinghouse
- Privilege of the floor at the Annual Meeting
- No vote at the Annual Meeting
- Not eligible to serve on NABP Executive Committee

NABP®

Drug Shortage Factors

- Approximately 87% of prescriptions are dispensed as generics[1]
- Approximately 88% of dollars are spent on brands (biologics, specialty drugs, etc.) [1]
- Generic prices have fallen by approximately 20% since 2019[1]
- Low drug prices of generics have contributed to ANDA holders not launching approved drugs to market, limiting suppliers of inexpensive generics in both solid dosage forms and injectables
- Since 2013, 42% of injectables receiving approved ANDAs have not be launched
- Manufacturing problems shutting down one generic manufacturer can reduce supplies drastically
- Injectables are by nature, difficult to make, further limiting firms entering the marketplace

[1] IQVIA - HDA DMC 3/12/2024

FDA

“There are fewer firms making older sterile injectable drugs, and there are a limited number of production lines that can make these drugs. The raw material suppliers the firms use are also limited in the amount they can make due to capacity issues at their facilities. This small number of manufacturers and limited production capacity for older sterile injectables, combined with the long lead times and complexity of the manufacturing process for injectable drugs, results in these drugs being vulnerable to shortage. When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs.”

https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages

FDA – Report on Drug Shortages

https://www.youtube.com/watch?v=u4Pe3bfcr7I

- The report identifies three root causes for drug shortages:
  - Lack of incentives for manufacturers to produce less profitable drugs;
  - The market does not recognize and reward manufacturers for “mature quality systems” that focus on continuous improvement and early detection of supply chain issues; and
  - Logistical and regulatory challenges make it difficult for the market to recover from a disruption.
- Limited number of major players in the generic drug market

Stimulant Shortages

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search

Morbidity and Mortality Weekly Report (*MMWR*)

Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults — United States, 2016–2021

Weekly / March 31, 2023 / 72(13);327–332

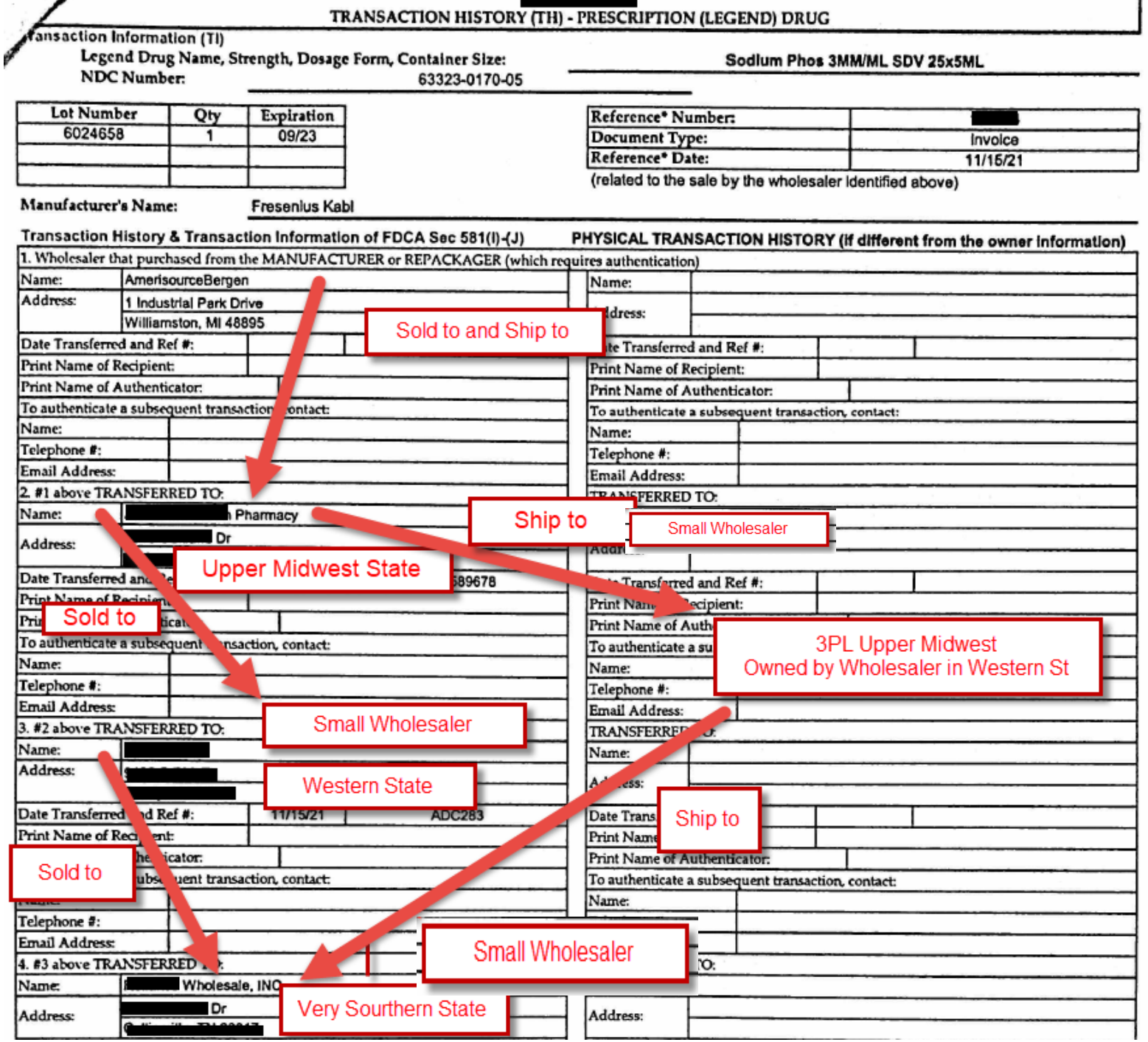
Melissa L. Danielson, MSPH[1]; Michele K. Bohm, MPH[2]; Kimberly Newsome, MPH[1]; Angelika H. Claussen, PhD[1]; Jennifer W. Kaminski, PhD[2]; Scott D. Grosse, PhD[3]; Lila Siwakoti, MPH[2]; Aziza Arifkhanova, PhD[2]; Rebecca H. Bitsko, PhD[1]; Lara R. Robinson, PhD[1] (VIEW AUTHOR AFFILIATIONS)

Stimulant Shortages

- Increase in demand
  - Relaxed telehealth policies (no in-person visit)
  - Increased access to mental health care through telehealth
- Established patients at pharmacies seeking prescriptions elsewhere due to the shortage, resulted in established patients at those pharmacies with fewer supplies
- Nonpayment for branded stimulants
- Imbalance of DEA-allocated raw active pharmaceutical ingredients
- Manufacturers not utilizing allocated resources (2022 & 2023)

DEA Response to Stimulant Shortage

- August 28, 2023, DEA made changes to the allocation quota process
  - Reduced the amount of drug inventory required to be on hand at manufacturers
  - Adjusted the process for manufacturers to voluntarily relinquish their quota allotments to shift allotments to other manufactures
- November 1, 2023, DEA announced steps to increase manufacturer transparency and receive real-time data on the status of drug production
  - Required drug manufacturers to submit anticipated production timelines in advance of receiving their quotas
  - Moved the quota application process to quarterly instead of annually
  - Monthly reporting by manufactures and distributors on the amount of drug product being produced and shipped
  - Specifying whether drug product allotment is domestic or imported



Drugs sold/ship to Pharmacy by Big 3 (WD-1)

Drug shipped to 3PL by Pharmacy. Drug sold to WD-2 that owns 3PL.

WD-2 that bought the drug from Pharmacy sells to another WD-3. 3PL ships drug to WD-3

WD-2 Business Model is buying drugs from pharmacies that purchase a couple of vials that are on allocations from the WD. This exacerbates the shortage when the WD buys hundreds vials from many pharmacies.

NABP
National Association of Boards of Pharmacy

Questions?

Attachment 2

Title 16. Board of Pharmacy
Order of Adoption

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

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

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) 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 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 automated drug delivery system license has been issued.
  (2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
  (3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/~~18~~23) entitled “Automated Drug Delivery System Self-Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
    (C) DEA registration number, expiration date, and date of most recent DEA inventory;
    (D) Hours of operation of the pharmacy; and
    (E) ADDS license number, address, and hours of operation.
  (2) The pharmacist-in-charge shall respond “yes”, “no”, or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
  (3) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
  (4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

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

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that ~~he or she~~ they have ~~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~~ drug delivery system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

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

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

(f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:

(1) The mechanical devices used as part of the automated drug delivery system to store, dispense, or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;

(2) The same policies and procedures required by Section 4427.2 of the BPC are used; and

(3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.

(g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliancewith federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:

(1) The mechanical devices used as part of the automated drug delivery system to store, dispense, or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;

(2) The same policies and procedures required by Section 4427.2 of the BPC are used; and

(3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-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, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, ~~and~~ 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.

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LEGEND: Proposed changes made to the current regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires that the pharmacy holding an automated drug delivery system (ADDS) license complete ~~an annual~~ a 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 **before July 1 of every odd-numbered year** by the pharmacist-in-charge of each pharmacy under BPC sections 4029 (Hospital Pharmacy) or ~~section~~ 4037 (Pharmacy). The pharmacist-in-charge (PIC) 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 this Self-Assessment.

All references to Business and Professions Code (BPC) are to Division 2, 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 the signed original must be readily available and retained in the pharmacy for three (3) years after performed.

Note: For a hospital pharmacy operating an AUDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the AUDS. The hospital pharmacy is required to comply with all other requirements including completing the ADDS Self-Assessment pursuant to BPC 4427.7(a). The PIC may complete a single self-assessment for all ADDS, if the mechanical devices used are the same manufacturer, are controlled by the same software system on a single server and use same policies and procedures. Attach a list of all unlicensed ADDS, their locations and hours of operation. [CCR 1715.1(f)]

Note: **For a licensed correctional pharmacy** operating more than one licensed automated drug delivery system at a single institution, the PIC may complete a single consolidated self-assessment for all licensed ADDS, if the mechanical devices used are the same manufacturer, are controlled by the same software system on a single server and use the same policies and procedures. Attach a list of all licensed ADDS and include the ADDS license number, manufacturer and model number. [CCR 1715.1(g)]

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: _____ **Zip Code:** _____

Phone: _____ **Fax number:** _____

Website: _____

Pharmacy License #: _____ **Expiration (Exp) Date:** _____

DEA Registration #: _____ **DEA Exp~~iration~~ Date:** _____ **DEA Inventory Date:** _____

Last ~~C2~~ Controlled Substance (CS) Inventory Reconciliation Date (CCR 1715.65(c)): _____

Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____ **RPH#**_____

PIC Email: _____

ADDS License #: _____ **ADDS Expiration Date:** _____

(Attach additional sheets if necessary)

ADDS Address: _____

City: _____ **Zip Code:** _____

ADDS Hours: **M-F:** _____ **Saturday** _____ **Sunday** _____

Please explain if the ADDS hours are different than the pharmacy:

_____

_____

Reason for completing self-assessment:

☐ Performing self-assessment before July 1 of every odd-numbered year. [BPC 4427.7, CCR 1715.1(a)]

☐ Completing a self-assessment within 30 days when a new ADDS license was issued. [BPC 4427.7, CCR 1715.1(b)(1)]

☐ Completing a self-assessment within 30 days when there was a change in PIC. [BPC 4427.7, CCR 1715.1(b)(2)]

☐ Completing a self-assessment within 30 days when there was a change in the licensed location of an ADDS to a new address. [BPC 4427.7, CCR 1715.1(b)(3)]

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)]

☐☐☐ 1.3 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration and dispensing to patients by a physician in a drug room or hospital emergency room when the pharmacy is closed. [BPC 4427.2(i), 4427.65, ~~BPC~~ 4056, ~~BPC~~4068]

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~~APDS **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~~AUDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (HSC)~~(Long Term Care (LTC))~~ that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2), HSC 1250, HSC 1261.6]

~~**Yes No N/A**~~

☐☐☐ 2.4 Provides pharmacy services through an AUDS in **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** or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029 of the Business and Professions Code, 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 of the Business and Professions Code. 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. [BPC 4427.2(i)]

☐☐☐ 2.8 **AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room)**, as defined in section 4056 of the Business and Professions Code, is used to provide doses administered to patients while in a licensed general acute care hospital and to dispense drugs to outpatients: [BPC 4056(f), (g), (h), 4427.2(i)]

- ☐ 2.8.1. Only if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued.
- ☐ 2.8.2. The physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius from the hospital pharmaceutical services by means of the method of transportation the patient states that they intend to use.
- ☐ 2.8.3. The quantity dispensed to any outpatient is limited to the amount necessary to maintain uninterrupted therapy during the period when the pharmaceutical services outside the hospital are not readily available or accessible and does not exceed a 72-hour supply. [BPC 4056, 4427.2(i)]

Yes No N/A

☐☐☐ 2.9 **AUDS located in the emergency room operated by a licensed hospital pharmacy**, as defined in subdivisions (a) and (b) of section 4029 of the Business and Professions Code, 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 subdivisions (a) and (b) of section 1250 of the Health and Safety Code**, and to dispense** to an emergency room patient if: [BPC 4068, 4427.2(i), HSC 11165(a)]

- ☐ 2.9.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 2.9.2. The drug is acquired by the hospital pharmacy.
- ☐ 2.9.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 2.9.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance and dispensing information is reported to the Department of Justice pursuant to section 11165 of the Health and Safety Code.
- ☐ 2.9.5. The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued and the prescriber reasonably believes a

pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

☐ 2.9.6. The quantity of drugs dispensed to any patient pursuant to this section is limited to the amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.

Note: Licensure of AUDS operated under these provisions is required.

☐☐☐ 2.10 **An AUDS may be located and operated in a facility licensed in CA with the statutory authority to provide pharmaceutical services**. [BPC 4427.65(a)(1)]

Type of Facility: _____

Statutory authority to provide pharmaceutical services (List code section): _____

Yes No N/A

☐☐☐ 2.11 **An AUDS may be located and operated in a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director**. [BPC 4427.3(b)(6), BPC 4427.65(a)(2)]

Type of Facility: _____

Statutory authority for type of Facility (List code section): _____

Please 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)]

☐ 3.4.1. Use of the ADDS is consistent with legal requirements.

☐ 3.4.2. The proposed location for installation of the ADDS meets the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

☐ 3.4.3. The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

☐ 3.4.4. The pharmacy's policy and procedures include 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), 4119.11(a)(9)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e), 4119.11(a)(9)]

☐☐☐ 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), 4119.11(a)(10)]

☐☐☐ 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), 4119.11(a)(11)]

☐☐☐ 3.10 The ADDS license~~(s)~~ is~~/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 section 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), 4427.65(c)(5)(D), HSC 1261.6(f)(4)]

☐☐☐ 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), BPC 4427.65(c)(5)(E), BPC 4119.11(f), HSC 1261.6(f)(5)]

☐☐☐ 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 of the Business and Professions Code, and, upon retrieval of the dangerous drugs and dangerous 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), BPC 4427.7(b)]

☐☐☐ 3.22 The record of quality assurance review, as provided in California Code of Regulation section 1711(e), is immediately retrievable in the pharmacy for at least one year from the date the record was created. [CCR 1711(f)]

☐☐☐ 3.23 An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the pharmacy's license. [CCR 1711(d), CCR 1711(f)]

~~❑❑❑ 3.24 The PIC of EACH ADDS completes a self-assessment of the pharmacy's compliance with federal and state pharmacy law and is performed [CCR 1715.1(a), (b)]:~~

- ~~Before July 1 of every odd-numbered year.~~
- ~~Within 30 days whenever a new ADDS licensed has been issued.~~
- ~~Within 30 days when there is a change in PIC.~~
- ~~When there is a change in the licensed location of an ADDS to a new address.~~

~~❑❑❑ 3.25 The PIC of an ADDS assesses the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1/22) entitled "Automated Drug Delivery System Self-Assessment." [CCR 1715.1(c)]~~

~~❑❑❑ 3.26 The PIC responds "yes", "no", or "not applicable" about whether the ADDS is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting. [CCR 1715.1(c)(2)]~~

~~❑❑❑ 3.27 For each "no" response, the PIC provides a written corrective action or action plan to come into compliance with the law. [CCR 1715.1(c)(3)]~~

~~❑❑❑ 3.28 The PIC initialed each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form. [CCR 1715.1(c)(4)]~~

~~❑❑❑ 3.29 The PIC has certified on the last page of the self-assessment that they are the PIC, has certified a timeframe within which any deficiency identified within the self-assessment will be corrected, and has acknowledged all responses are subject to verification by the Board of Pharmacy. The certification is made under penalty of perjury of the laws of the State of California and the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form. [CCR 1715.1(c)(5)]~~

~~Yes No N/A~~

~~❑❑❑ 3.30 The ADDS owner has certified the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the ADDS license issued by the Board. The certification is made under penalty of perjury of the laws of the State of California with an original handwritten signature or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form. [CCR 1715.1(c)(6)]~~

~~❑❑❑ 3.31 Each self-assessment is completed in its entirety and kept on file in the underlying pharmacy for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]~~

~~❑❑❑ 3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]~~

~~☐☐☐ 3.33 The PIC ensures the following: [CCR 1715.65(h)]~~

~~☐ 3.33.1 All controlled substances added to an ADDS are accounted for.~~
~~☐ 3.33.2 Access to the ADDS is limited to authorized facility personnel.~~
~~☐ 3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.~~
~~☐ 3.33.4 Confirmed losses of controlled substance are reported to the board.~~

Yes No N/A

☐☐☐ 3.24 The pharmacy's inventory reconciliation report prepared at least once every three months for federal Schedule II controlled substances, includes the federal Schedule II controlled substances stocked in the ADDS. [CCR 1715.65(a)(1)]

☐☐☐ 3.25 The pharmacy's inventory reconciliation report prepared at least once every 12 months for alprazolam 1mg/unit, alprazolam 2mg/unit, Tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, includes these controlled substances stocked in the ADDS. [CCR 1715.65(a)(2)]

☐☐☐ 3.26 Inventory activities are performed at least once every two years from the performance of the last inventory activities for each controlled substance that is not listed as a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml and includes the controlled substances stocked in the ADDS. [CCR 1715.65(a)(3)(B)]

☐☐☐ 3.27 For any controlled substance stocked in the ADDS that is not a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, the pharmacy prepares an inventory reconciliation report for the identified loss of that controlled substance in the ADDS no later than three months after the discovery of the reportable loss and is completed if the loss is discovered either by the inventory activities as identified in Section 3.26 above or any other manner. [CCR 1715.65(a)(3)(A)]

☐☐☐ 3.28 A physical count, not an estimate, of the federal controlled substances in the ADDS is taken for the inventory reconciliation reports, except for an inpatient hospital pharmacy or licensed correctional pharmacy where the inventory in the ADDS may be accounted for using means other than a physical count. [CCR 1715.65(c)(1), CCR 1715.65(h)]

☐☐☐ 3.29 The PIC or the consulting pharmacist for a licensed clinic reviews all inventory activities performed and inventory reconciliation reports prepared in accordance with CCR 1715.65 and has established and maintained secure methods to prevent losses of federal controlled substances. [CCR 1715.65(b)]

☐☐☐ 3.30 The pharmacy has written policies and procedures developed for performing the inventory activities and preparing the inventory reconciliation reports in accordance with CCR 1715.65

that includes the inventory of federal controlled substances stored in the ADDS. [CCR 1715.65(b)]

☐☐☐ 3.31 The original board-issued ADDS permit and current renewal are posted at the ADDS premise, where they may be clearly read by the public. [BPC 4058]

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 pharmacy owner or hospital administrator of the ADDS shall sign the Certification Acknowledgment on page ~~33~~ 48 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~~

- APDS adjacent to the secured pharmacy area~~ (or)~~
- APDS located in a Medical Office~~s~~
- APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice
- APDS located at a clinic pursuant to HSC 1204, 1204.1, BPC 4180, or 4190.

☐ SECTION 6: ~~=~~ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6.

~~☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.~~

☐ SECTION ~~8~~7:– ADDS operated by a correctional clinic pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

☐ SECTION ~~9~~8:

- Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 ~~(~~when the hospital pharmacy is closed and no pharmacist is available~~)~~.
- Drug Room: AUDS used for dispensing pursuant to BPC 4056.

☐ SECTION 9:

- AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)
- AUDS through a jail, youth detention facility, or other licensed correctional facility where drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

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 A 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 of the United States Code (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 42 USC 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_____

_____

_____

_____

_____

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]~~

Yes No N/A

☐☐☐ 4.~~9~~8 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)]~~

☐☐☐ 4.9~~13~~ The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10), 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

~~**Yes No N/A**~~

☐☐☐ 4.10~~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), CCR 1713(f)]

Yes No N/A

☐☐☐ 4.11~~15~~ The operating pharmacy of an APDS has completed a~~n annual~~ biennial Self-Assessment pursuant to CCR 1715.1 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: _____
Reason: ☐ Biennial; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

~~☐☐☐ 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~~12 The underlying operating pharmacy is solely responsible for: [BPC 4119.11(a)(5), (6)]

☐ 4.12.1 The security of the APDS. [BPC 4119.11(a)(5)]
☐ 4.12.2 The operation of the APDS. [BPC 4119.11(a)(5)]
☐ 4.12.3 The maintenance of the APDS. [BPC 4119.11(a)(5)]
☐ 4.12.4 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: _____
_____
_____
_____
_____
_____
_____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.1~~9~~3 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~~14 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~~14.1. 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~~14.2. Transportation of removeable pockets, cards, drawers or similar technology o~~O~~r 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~~14.3. 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~~15 ~~The~~ A 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~~16 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

☐ 4.16.1. All controlled substances added to the ADDS/APDS are accounted for;

☐ 4.16.2. Access to ADDS/APDS is limited to authorized facility personnel;

☐ 4.16.3. An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and

☐ 4.16.4. 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~~17 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~~18 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~~19 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~~20 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐ 4.2~~7~~1.1 The pharmacy has developed, ~~and~~ implemented, and maintained~~s~~ written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1)~~(d)(1)(F)~~, CCR 1713(e)]

- ☐ 4.21.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 4.21.1.2 Determining~~e~~ and applying inclusion criteria regarding which drugs~~,~~ and devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.
- ☐ 4.21.1.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.
- ☐ 4.21.1.4 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.
- ☐ 4.21.1.5 Orienting patients on the 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.
- ☐ 4.21.1.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event that the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐ 4.2~~7~~1.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs 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~~

☐ 4.2~~7~~1.3 The ~~device~~ APDS 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), CCR 1713(d)(2)]

☐ 4.2~~7~~1.4 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)]

☐ 4.2~~7~~1.5 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~~s~~ contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]

☐ 4.2~~7~~1.6 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)]

☐ 4.2~~7~~1.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐ 4.2~~7~~1.8 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)]~~

Yes No N/A

☐☐☐ 4.2~~8~~2 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.2~~9~~3 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~~24 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.~~31~~25 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.~~32~~26 Medication guides are provided on required medications. [~~(~~21 CFR 208.1]~~)~~

☐☐☐ 4.27 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

- ☐ 4.27.1. The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.
- ☐ 4.27.2. The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.
- ☐ 4.27.3. The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

☐ 4.27.4. Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

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~~28 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~~29 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), CCR 1713(e)]:

- ☐ 4.29.1 Maintaining the security of the APDS and dangerous drugs and devices within the APDS.
- ☐ 4.29.2 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.
- ☐ 4.29.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 4.29.4 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.

☐ 4.29.5 Orienting patients on use of the 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.

☐ 4.29.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS ~~in the event~~ if the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.3~~7~~0 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)~~4105.5(c)(2)~~]

☐☐☐ 4.3~~8~~1 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~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~~ (Check the Appropriate Box)

☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**

☐ **APDS LOCATED IN A MEDICAL OFFICE~~S (OR)~~**

☐ **APDS LOCATED WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE ~~(OR).~~**

☐ **APDS LOCATED AT A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.**

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), CCR 1713(f)]

~~☐☐☐ 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

☐☐☐ 5.2 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

- ☐ 5.2.1. A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to the patient.
- ☐ 5.2.2. The APDS has a means of identifying each patient and only release that patient's prescription medication to the patient or patient's agent.
- ☐ 5.2.3. The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
- ☐ 5.2.4. Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

~~**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)]

Yes No N/A

☐☐☐ 5.6 ~~The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS.~~ All prescribed drugs and devices dispensed to the patient from the APDS for the first time are accompanied by a consultation conducted by a California licensed pharmacist. 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 ~~P~~pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- ☐ 5.7.1. All controlled substances added to the ADDS/APDS are accounted for;
- ☐ 5.7.2. Access to ADDS/APDS is limited to authorized facility personnel;
- ☐ 5.7.3. An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 5.7.4. 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~~8 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~~9 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~~10 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~~11 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~~12 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~~13 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~~14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.~~21~~15 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]

Yes No N/A

☐☐☐ 5.~~22~~16 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.~~23~~17 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.~~24~~18 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~~19 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~~20 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~~21 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are maintained and reviewed annually: [BPC 4427.6(a)~~= 4427.6(a)(6)~~, CCR 1713(e)]

- ☐ 5.21.1. Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 5.21.2. Determining~~e~~ and applying inclusion criteria regarding which drugs and~~,~~ devices are appropriate for placement in the APDS and for which patients.
- ☐ 5.21.3. Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 5.21.4. 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.
- ☐ 5.21.5. 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.
- ☐ 5.21.6. 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~~22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~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~~ THAT COMPLIES WITH HSC 1261.6

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means any 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), 1250]

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~~1 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~~2 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~~3 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~~3.1. 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~~3.2. 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~~3.3. 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~~4 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~~5 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)]

☐☐☐ 6.6 A Schedule II controlled substance for a patient in a licensed skilled nursing facility or licensed intermediate care facility is dispensed only after the pharmacist has received:

☐ 6.6.1 An **orally transmitted** prescription for a Schedule II controlled substance from the prescriber and only after the pharmacist reduced the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy. The prescription must contain: [HSC 11167.5(a)]

- ☐ 6.6.1.1. The date the prescription was orally transmitted by the prescriber.
- ☐ 6.6.1.2. The name of the person for whom the prescription was authorized.
- ☐ 6.6.1.3. The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient.
- ☐ 6.6.1.4. The name and quantity of the controlled substance prescribed.
- ☐ 6.6.1.5. The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
- ☐ 6.6.1.6. The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.

☐ 6.6.2 Prior to filling a prescription for a Schedule II controlled substance that has been **electronically transmitted,** the pharmacist has produced, signed, and dated a hard copy prescription. The prescription must contain: [HSC 11167.5(a)]

- ☐ 6.6.2.1. The date the prescription was electronically transmitted by the prescriber;
- ☐ 6.6.2.2. The name of the person for whom the prescription was authorized;
- ☐ 6.6.2.3. The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient;
- ☐ 6.6.2.4. The name and quantity of the controlled substance prescribed;
- ☐ 6.6.2.5. The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
- ☐ 6.6.2.6. The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.
- ☐ 6.6.2.7. The prescription contains the signature of the person who received the controlled substance for the licensed skilled nursing facility or licensed intermediate care facility.

☐ 6.6.3 An original Schedule II prescription is written on a form that complies with Health and Safety Code section 11162.1. [HSC 11164(a)]

☐ 6.6.4 An original Schedule II prescription is written with the "11159.2 exemption" for the terminally ill. [HSC 11159.2]

☐ 6.6.5 In an emergency where failure to issue the prescription may result in loss of life or intense suffering, a Schedule II controlled substance may be dispensed from a prescription transmitted orally or electronically by a prescriber or written on a form not as specified in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]

- ☐ 6.6.5.1. The order contains all information required by subdivision (a) of Section 11164.

☐ 6.6.5.2. If the order is written by the prescriber, the prescription is signed, and dated by the prescriber in ink.

☐ 6.6.5.3. If the prescription is orally or electronically transmitted, it must be reduced to hard copy prior to dispensing the controlled substance.

☐ 6.6.5.4. The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of HSC 11162.1 by the seventh day following the transmission of the initial order.

☐ 6.6.6. An electronic prescription (e-script) for controlled substances that is received from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]

Yes No N/A

☐☐☐ 6.~~8~~7 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.~~

☐☐☐ 6.~~10~~8 The pharmacy operating the ADDS has completed a~~n~~ biennial Self-Assessment pursuant to BPC 4427.7(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~~9 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), HSC 1261.6(c), (g)]

~~☐☐☐ 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)]~~

~~Yes No N/A~~

☐☐☐ 6.~~13~~10 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~~11 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~~12 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~~13 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~~14 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~~15 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~~16 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~~17 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)]~~

Yes No N/A

☐☐☐ 6.~~23~~18 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~~19 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~~20 If the ADDS allows licensed personnel to have access to multiple drugs and ~~are~~ is not patient specific in its~~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)]~~)~~.

Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs and are not patient specific in their design, is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]

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~~21 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)]

Yes No N/A

☐☐☐ 6.22 Records of inspections completed by the pharmacist are kept for at least three years. [22 CCR 70263(f)(3)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.~~23~~23 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.~~24~~24 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.~~25~~25 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.~~26~~26 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~~27 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)]

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule II 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 II controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule II 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.

Yes No N/A

☐☐☐ 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(e).

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

☐☐☐ 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: _____

☐☐☐ 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)]

Yes No N/A

☐☐☐ 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_____

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~~7: ADDS OPERATED BY A CORRECTIONAL CLINIC PURSUANT TO BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2)

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7~~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)]

☐☐☐ 7~~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 Co~~n~~de, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. ~~(~~[BPC 4187(a)~~)~~].

~~Yes No N/A~~

☐☐☐ 7~~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 direction~~s~~ 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.

☐☐☐ 7~~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)]

☐☐☐ 7~~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)]

☐☐☐ 7~~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)]

☐☐☐ 7~~8~~.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 7~~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)]

☐☐☐ 7~~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)]

☐☐☐ 7~~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

☐☐☐ 7~~8~~.1~~2~~1 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)]

☐☐☐ 7~~8~~.1~~3~~2 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)]

☐☐☐ 7~~8~~.1~~4~~3 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~5~~4 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 502~~4~~4~~2~~.2 of the Penal Code and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services ~~Policies and Procedures~~ Health Care Department Operations Manual in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

Yes No N/A

☐☐☐ 7~~8~~.1~~6~~5 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)]

☐☐☐ 7~~8~~.1~~7~~6 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]

☐☐☐ 7~~8~~.1~~8~~7 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~~ California Correctional Health Care Services Health Care Department Operations Manual ~~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)]

☐☐☐ 7~~8~~.1~~9~~8 All policies and procedures are maintained either in an electronic form or paper form at the location where the ~~automated drug system~~ ADDS 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

☐☐☐ 7~~8~~.~~20~~19 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 7~~8~~.~~21~~20 Drugs removed from the ~~automated drug system~~ ADDS ~~is~~ are 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,~~ Where administration of the drug is necessary before a pharmacist has reviewed the prescription and if, in the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the ~~automated drug delivery system~~ ADDS 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~~ California Correctional Health Care Services Health Care Department Operations Manual. Any removal of the medication from an ~~automated drug delivery~~ ADDS ~~system~~ is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 7~~8~~.~~22~~21 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~~ ADDS, an inspection of the ~~automated drug delivery system~~ ADDS 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

☐☐☐ 7~~8~~.~~23~~22 Drugs removed from the ADDS ~~is~~ are 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)]

☐☐☐ 7~~8~~.~~24~~23 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)]

☐☐☐ 7~~8~~.~~25~~24 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)]

☐☐☐ 7~~8~~.~~26~~25 Drugs from the ADDS in the correctional clinic are removed by a person authorized to stock the ADDS, or 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

☐☐☐ 7~~8~~.~~27~~26 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~~ are 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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SECTION ~~9~~8:

- ☐ **HOSPITAL PHARMACY: AUDS USED FOR DISPENSING PURSUANT TO BPC 4068 (WHEN THE HOSPITAL PHARMACY IS CLOSED AND NO PHARMACIST IS AVAILABLE.**
- ☐ **DRUG ROOM: AUDS ~~used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)~~ USED FOR DISPENSING PURSUANT TO BPC 4056**

Please Note: Hospital pharmacies and drug rooms must also complete Section 6 for ADDS used for administration. This section addresses additional requirements for hospital pharmacies and drug rooms operating an ADDS used for dispensing.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8~~9~~.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states they ~~he/she~~ intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a), (f)]

☐☐☐ ~~8~~9.2 ~~The~~ Where the prescriber in a hospital emergency room dispenses a dangerous drug, including a controlled substance, from the AUDS to an emergency room patient, the following conditions apply [BPC 4068(a)]:

- ☐ 8.2.1 ~~when t~~The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 8.2.2 The drugs ~~is~~are acquired by the hospital pharmacy.
- ☐ 8.2.3 The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 8.2.4 The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.
- ☐ 8.2.5 The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patients.
- ☐ 8.2.6 The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. ~~[BPC 4068(a)(1-6)]~~
- ☐ 8.2.7 The prescriber ensures that the label on the drug contains all the information required by BPC section 4076.

Yes No N/A

☐☐☐ 8.3 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]

~~**Yes No N/A**~~

☐☐☐ ~~9.3~~8.4 The prescriber ensures the label on the drug contains all the information required by BPC 4076 and~~,~~ CCR 1707.5.

☐☐☐ ~~9.4~~8.5 The federal warning label~~s~~ prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ ~~9.5~~8.6 The prescription drug is 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 request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ ~~9.6~~8.7 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4068(a)(4), HSC 11165(d)]

☐☐☐ ~~9.7~~8.8 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ ~~9.8~~8.9 The hospital has written policies and procedures to ensure each patient receives information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. [BPC 4074(e)]

~~☐☐☐ 9.9 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]~~

~~Yes No N/A~~

☐☐☐ 8.10 Medication guides are provided on required medications. [21 CFR 208.24]

☐☐☐ 8.11 Boxed warning "Black Box" information is in conformance with 21 CFR 201.57(c).

☐☐☐ 8.12 Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug prominently displays on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." [BPC 4076.7]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____
_____
_____
_____
_____

SECTION 9 – AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH DETENTION FACILITY, OR OTHER LICENSED CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED WITHIN THE FACILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR PURSUANT TO BPC 4187.4, 4427.3(b)(6), or 4427.65(a)(2).

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 Review of the drugs contained within, and the operation and maintenance of, the ADDS is done in accordance with law and is the responsibility of the pharmacy. A pharmacist conducts the review on a monthly basis, which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4427.65(c)(7)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____
_____
_____
_____

B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 9.2 The stocking of an ADDS is performed by a pharmacist. If the ADDS 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 the following conditions are met: [BPC 4427.65(c)(6)]

- ☐ 9.2.1. 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.
- ☐ 9.2.2. 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.
- ☐ 9.2.3. 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.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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_____

C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [BPC 4427.65(c)(2)]

For Sections 9.5-9.7: When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [BPC 4427.65(c)(4)]:

☐☐☐ 9.5 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 are 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. [BPC 4427.65(c)(4)(A)]

☐☐☐ 9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC 4427.65(c)(4)(B)]

☐☐☐ 9.7 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 the ADDS pursuant to the order of the prescriber for emergency or immediate administration to

the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist. [BPC 4427.65(c)(4)(C)]

For Sections 9.8-9.12: When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3 and Article 25 in Chapter 9, Division 2 of the BPC, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:

☐☐☐ 9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]

☐☐☐ 9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(5)(B)]

Yes No N/A

☐☐☐ 9.10 The pharmacy providing services to the facility pursuant to Article 25 in Chapter 9, Division 2 of the BPC controls the access to the drugs stored in the ADDS. [BPC 4427.65(c)(5)(C)]

☐☐☐ 9.11 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. When the prescriber's order requires a dosage variation of the same drug, licensed personnel has access to the drug ordered for that scheduled time of administration. [BPC 4427.65(c)(5)(F)]

☐☐☐ 9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if the ADDS has electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to the patient. [BPC 4427.65(c)(5)(G)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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_____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 9.13 Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years. [BPC 4427.65(c)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 9.14 The pharmacy operating the AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the AUDS. [BPC 4427.65(b)]

☐☐☐ 9.15 The facility and the pharmacy have developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)]

☐☐☐ 9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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)

ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR ADMINISTRATOR OPERATING THE ~~OF~~ ADDS:

I, ~~(please print)~~ _____ [print name and title], hereby certify under penalty of perjury under ~~of~~ the laws of the State of California that I have full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein are true, correct, and complete. ~~read and reviewed this completed self-assessment.~~ Further, I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.

Signature _____Date _____
(Owner or Administrator)

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have corrected the 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)

ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR ADMINISTRATOR OPERATING THE ~~OF~~ ADDS:

I, ~~(please print)~~ _____ [print name and title], hereby certify under penalty of perjury under ~~of~~ the laws of the State of California that I have full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein are true, correct, and complete. ~~read and reviewed this completed self-assessment.~~ Further, I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.

Signature _____Date _____
(Owner or Administrator)

Attachment 2

Supplement

ADDS Self-Assessment

Office of Administrative Law Comments

List of Issues

1. **Clarity – CCR § 1715.1(b)(2):** The language of the regulation conflicts with the Board's description of the effect of the regulation. The Board proposes the following amendment: "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~~." The following description of this change is provided in the Initial Statement of Reasons (the "ISR"):

> Subdivision (b)(2) is amended to strike "change in the pharmacist-in charge, and he or she becomes the new pharmacist in charge," and replaced with "new pharmacist-in-charge" in order to streamline the language and remove gendered language consistent with [Assembly Concurrent Resolution No. 260 of 2018].

Contrary to the description in the ISR, the Board is not changing the phrase "change in the pharmacist-in-charge" to "new pharmacist-in-charge".

2. **Clarity – CCR § 1715.1(c)(6):** Changes to the certifications in Form 17M-112 entitled "Automated Drug Delivery System Self-Assessment" (the "Form") permitting a hospital administrator to make the certification previously required to be made only by the owner of the hospital necessitates a similar amendment to CCR § 1715.1(c)(6).

3. **Clarity – CCR § 1715.1(f)(3):** A commenter wanted to know how to approach this requirement in connection with AUDS that does not have a license number and expiration date due to the exemption in Bus. & Prof. Code § 4427.2(i). In the Final Statement of Reasons (the "FSR"), the Board states that "the licensee would not document this information as it does not exist." The Board should specify this in the proposed regulations.

4. **Clarity – Form, pg. 1:** Similar to Issue #1, *supra*, the language of the regulation conflicts with the Board's description of the effect of the regulation. The Board proposes the following amendment: "The pharmacist-in-charge (PIC) must also complete a self-assessment within 30 days whenever . . . there is a change in the pharmacist-in-charge~~ and becomes the new pharmacist-in-charge of an automated drug delivery system~~[.]" The following description of this change is provided in the ISR: "[T]he phrase 'a new pharmacist' was added to the verb 'becomes' for grammatical compliance, and the word 'new' before 'pharmacist-in-charge' was deleted as redundant." Contrary to the description in the ISR, the Board is not changing the phrase "becomes the new pharmacist-in-charge" to "becomes a new pharmacist".

5. **Consistency – Form, Note, pg. 1:** The phrase "For a hospital pharmacy operating an ADDS pursuant to BPC 4427.2(i)" needs to be changed so that,

instead of a reference to ADDS, it is a reference to AUDS, which is what Bus. & Prof. Code § 4427.2(i) applies to.

6. **Clarity – Form, Note, pg. 1:** The citation to CCR § 1715.1(g) at the end of the paragraph needs to be changed to cite subsection (f) instead.

7. **Clarity – Form, pg. 1:** The Board uses the acronym "CS" to refer to "controlled substances" without ever defining the acronym as such.

8. **Clarity/Necessity – Form, Section 2.8:** The Board provides an insufficient explanation of the proposed addition of this section, which is also unclear. The Board states, "This section is added to ensure that the PIC is aware of, and that the drug room facility is operating its AUDS in compliance with, the requirements of BPC 4056(f)-(h)." However, it is not clear how this section is a restatement of the requirements in the cited statutory provisions. Specifically, this section appears to be a restatement of Bus. & Prof. Code § 4056(f), (g), and (h), but it is unclear how the Board arrived at the proposed section. (NOTE: This issue was raised in Comment #6. There, the commenter recommended that this section be amended to separate the requirements. The commenter also suggested that this section be shortened for ease of understanding. In the FSR, the Board rejected this comment, noting "that statutes are not taken separately, but collectively establish the requirements.")

9. **Clarity – Form, Section 2.9:** There are two issues:

    9.1. The language of the regulation conflicts with the Board's description of the effect of the regulation. In the ISR, the Board states that the following sentence is being added to the end of this new section: "Please refer to FAQs for additional information." However, no such sentence is being added, nor does the Form contain any FAQs.

    9.2. The word "solely" needs to be included in the text after the word "used" to align with Bus. & Prof. Code § 4427.2(i).

10. **Consistency – Form, Section 2.9:** Bus. & Prof. Code § 4427.2(i) exempts from the requirement of obtaining an ADDS license pursuant to that statute an AUDS operated by a licensed hospital pharmacy, as defined in Bus. & Prof. Code § 4029, and 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 Health & Saf. Code § 1250(a) and (b). But the Board, in restating provisions from this statute, proposes to add the following note: "Licensure of AUDS operated under these provisions is required." How does the Board reconcile this regulation with Bus. & Prof. Code § 4427.2(i), which appears to exempt licensure?

11. **Consistency – Form, Section 2.9.4:** Section 2.9.4 is a restatement of Bus. & Prof. Code § 4068(a)(4). Here, the Board proposes to replace the statutory phrase "and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code" with the phrase "and controlled substances dispensing information is reported to the Department of Justice pursuant to section 11165 of the Health and Safety Code". Are schedule II, III, and IV controlled substances the only categories of controlled substances? Health & Saf. Code § 11165(a) also lists schedule V controlled substances, so the proposed regulation may be more expansive than the statutory provision. Also, this change is not discussed in the ISR.

12. **Consistency – Form, Section 2.9.6:** Section 2.9.6 is a restatement of Bus. & Prof. Code § 4068(a)(6). Bus. & Prof. Code § 4068(a)(6) states, "The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply." In restating this provision, the Board is omitting the phrase "during the period when pharmacy services outside the hospital are not readily available or accessible", thereby changing the scope of the regulation.

13. **Clarity and Consistency – Form, Section 2.10:** This provision simply states, "A facility licensed in CA with the statutory authority to provide pharmaceutical services." This regulation is followed by a citation to Bus. & Prof. Code § 4427.65(a)(1). In the ISR, the Board explains, "This subsection is added to educate and ensure that the PIC is aware that an ADDS could be placed in a facility licensed in California that can provide pharmaceutical services [pursuant to BPC 4427.65(a)(1)]." However, nothing in the proposed regulation states that it pertains to where an AUDS is located and operated. This is because the Board omitted the context provided by Bus. & Prof. Code § 4427.65(a).

14. **Clarity – Form, Section 2.10:** The Board is also requiring that the PIC state the type of facility in question. A commenter requested that the Board include a list of facility types for the PIC to select from instead of utilizing an open-ended question that is subject to the PIC's interpretation. The Board rejected this comment, stating, "The form includes related references for the PIC to consult should they need additional clarification on which types of facilities are eligible." However, no such facility types are listed in the cited statute, Bus. & Prof. Code § 4427.65(a)(1). As such, it appears as though this requirement in the Form is unclear to those directly affected.

15. **Clarity and Consistency – Form, Section 2.11:** This issue is similar to Issue #13, *supra*. This provision simply states, "Jail, youth detention facility, or other

correctional facility where drugs are administered within the facility under the authority of the medical director." This regulation is followed by a citation to Bus. & Prof. Code §§ 4427.3(b)(6) and 4427.65(a)(2). In the ISR, the Board explains, "This subsection is added to educate and ensure that the PIC is aware that an ADDS could be placed in a jail, youth detention facility, or other correctional facility [pursuant to BPC 4427.65(a)(2)]." However, nothing in the proposed regulation states that it pertains to where an AUDS is located and operated. This is because the Board omitted the context provided by Bus. & Prof. Code § 4427.65(a).

16. **Clarity and Consistency – Form, Section 3.15:** The Board proposes to add a citation to CCR § 4119.11(a)(3). However, this statute applies solely to an APDS, and this section applies to an ADDS. Also, the scope of the restatement is more expansive when applied to CCR § 4119.11(a)(3). Specifically, the regulations apply to "drugs ***and devices***" and deems those to be "part of the inventory ***and the responsibility***" of the pharmacy, while the statute is limited to "drugs" and "part of the inventory", respectively.

17. **Clarity – Form, Section 3.17:** Section 3.17 states, "Access to the ADDS is controlled and tracked using an identification or password system or biosensor." Health & Saf. Code § 1261.6(f)(5) states, "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." The citation to Health & Saf. Code § 1261.6(f)(5) appears to be inappropriate.

18. **Clarity – Form, Section 3.18:** Bus. & Prof. Code § 4427.65(c)(5)(D) is not an appropriate citation for this section.

19. **Clarity and Consistency – Form, Section 3.21:** Bus. & Prof. Code § 4119.11(j) is being added as a citation, but the scope of the regulation is different. First, the statute is limited to recordkeeping and quality assurance requirements ***pursuant to Ch. 9 of Div. 2 of the Bus. & Prof. Code***, while the regulation applies to requirements "established in pharmacy law and regulations". Second, the statute applies to an APDS license, while the regulation applies to an ADDS license.

20. **Consistency – Form, Section 3.24:** In attempting to restate a requirement from CCR § 1715.65(a)(1), the Board added a requirement that the required inventory reconciliation report "includes the federal Schedule II controlled substances stocked in the ADDS". No explanation is provided for this additional requirement, which presumably should also be added to CCR § 1715.65(a)(1).

21. **Consistency – Form, Section 3.25:** There are two issues:

21.1. In attempting to restate a requirement from CCR § 1715.65(a)(2), the Board added a requirement that the required inventory reconciliation report "include [the listed] controlled substances stocked in the ADDS."

21.2. Regarding promethazine and codeine, the specified volume in CCR § 1715.65(a)(2)(D) is "6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product." In Section 3.26, this is restated differently as "promethazine/codeine 6.25mg/10mg/5ml".

22. **Consistency – Form, Section 3.26:** Issues #20, 21.1, and 21.2, *supra*, are present here due to restatements of Sections 3.24 and 3.25 in this section.

23. **Consistency – Form, Section 3.27:** A cross-reference to Section 3.26 needs to be added between the phrases "the inventory activities" and "or any other manner" to align with a similar cross-reference in the cited section, CCR § 1715.65(a)(3)(A). This is because Section 3.26 is a restatement of CCR § 1715.65(a)(3)(B), which is cross-referenced in CCR § 1715.65(a)(3)(A).

24. **Consistency – Form, Section 3.28:** To align with CCR § 1715.65(h)—which this section attempts to restate—the Board needs to specify that "correctional pharmacy" refers to a ***licensed*** correctional pharmacy.

25. **Consistency – Form, Section 3.29:** The Board added a parenthetical citation to Bus. & Prof. Code §§ 4180 and 4190 following the phrase "[t]he PIC or the consulting pharmacist for a clinic" even though no such citation is included in CCR § 1715.65(b), which this section attempts to restate.

26. **Form, Section 3.30:** There are two issues:

26.1. **Consistency:** In attempting to restate a requirement from CCR § 1715.65(b), the Board added a requirement that the required inventory reconciliation reports "include[] the inventory of federal controlled substances stored in the ADDS."

26.2. **Clarity:** In the citation at the end of this paragraph, the Board should clarify that this is a citation to CCR § 1715.65***(b)***.

27. **Clarity and Consistency – Form, Table of Contents, pg. 10:** The section descriptions listed on page 10 need to align with the descriptions of each respective section where it appears later on in the Form.

28. **Consistency – Form, Section 4.24.1.2:** Are "drugs and devices" and "medications" used interchangeably? In the ISR, the Board explains that changes to this section are necessary "in order to mirror the language specified in CCR 1713(e)." That change is to add the phrase "including when consultation

is needed" at the end of the sentence. However, Section 4.24.1.2 uses the phrase "drugs and devices" while CCR § 1713(e) uses the phrase "medication" in outlining the scope of this provision.

29. **Clarity – Form, Section 4.24.2:** The proposed addition of CCR § 1713(d)(1) as a citation is inappropriate, as the cited section does not support this provision.

30. **Clarity – Form, Section 4.24.3:** The proposed addition of CCR § 1713(d)(3) as a citation is inappropriate, as the cited section does not support this provision.

31. **Consistency – Form, Section 4.30:** The word "as" between "patients" and "provided" needs to be deleted to align with CCR § 1713(d), which this section is intended to mirror.

32. **Consistency – Form, Section 4.30.4:** The word "deliver" needs to be corrected to "delivery", as the latter is the word used in CCR § 1713(d)(3), which this section is intended to mirror.

33. **Clarity – Form, Section 5:** There are two issues. First, the ISR states, "The PIC will check the box that applies to the APDS being utilized." This instruction should be added to the self-assessment. Also, regarding the third box, the phrase "a location" needs to be changed to "located" as a grammatical correction.

34. **Consistency – Form, Section 5.2.1:** The word "deliver" needs to be corrected to "delivery", as the latter word is the one used in CCR § 1713(d)(1), which this section is intended to mirror.

35. **Clarity and Consistency – Form, Section 6A:** I am not sure that the proposed changes to the first paragraph are appropriate. While a citation to subdivision (n) of Health & Saf. Code § 1250 needs to be added, the citation to Health & Saf. Code § 1261.6(a)(2) at the end of the paragraph should probably remain. (Note: This issue was also raised in Comment #9. There, the commenter recommended that all requirements listed within Section 6 and the General Requirements be amended to specify the individual types of facilities to avoid confusion and to clarify that this section does not apply to general acute care hospitals and acute care psychiatric facilities. In the FSR, the Board rejected this comment, stating, *inter alia*, "The board noted that the language on the form mirrors the statute, which ensures consistency of information and provides the specific legal sections that the pharmacist-in-charge can refer to if clarification is needed.")

36. **Clarity – Form, Old Section 6.3:** In the ISR, the Board states that this section is being deleted because "it is duplicative with subsection 3.24." However, nothing similar to Section 6.3 is located in Section 3.24.

37. **Clarity – Form, New Section 6.3:** The Board proposes to add Bus. & Prof. Code § 4427.4(e)(1) as a citation at the end of this paragraph, but this citation is inappropriate since the paragraph is substantively different than the other cited statute.

38. **Clarity – Section 6.3.1:** This issue is similar to Issue #37, *supra*. The Board proposes to add Bus. & Prof. Code § 4427.4(e)(1) as a citation at the end of this paragraph, but this citation is inappropriate since the paragraph is substantively different than the other cited statute.

39. **Clarity and Consistency – Form, Sections 6.6.3-6.6.5:** Why are these self-assessments limited to Schedule II controlled substances when the cited statutes apply to more than Schedule II controlled substances? For example, re: Section 6.6.3, the cited statute (Health & Saf. Code § 11164(a)) applies to classified substances in Schedule II, III, IV, and V.

40. **Consistency – Form, Section 6.6.3:** There are exceptions authorized by Health & Saf. Code § 11164(b) that are not included.

41. **Consistency – Form, Section 6.6.5.2:** The Board did not successfully mirror language in Health & Saf. Code § 11167(b). Health & Saf. Code § 11167(b) requires, in pertinent part, "Any written order is signed and dated by the prescriber in ink[.]" The Board's attempt to restate this requirement in Section 6.6.5.2 resulted in the following provision: "<u>If the order is written by the prescriber, the prescription is in ink, signed, and dated by the prescriber.</u>" This is substantively different than the statute in two ways. First, the Board is requiring that the prescription be written in ink, while the "ink" requirement in the statute only applies to signing and dating the prescription. Second, Section 6.6.5.2 can be interpreted to only require the prescription to be in ink (i.e., the "ink" requirement in the regulation does ***not*** extend/apply to signing and dating the prescription).

42. **Consistency – Form, Section 6.6.5.3:** In mirroring a requirement in Health & Saf. Code § 11167(b), the Board omitted an important requirement. Health & Saf. Code § 11167(b) requires, in pertinent part, "[T]he pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance." Section 6.6.5.3 omits the requirement that this be done "prior to dispensing the controlled substance."

43. **Consistency – Form, Section 6.6.5.4:** The word "prescription" needs to be added between "substance" and "form" to align with the language in Health & Saf. Code § 11167(c), which this provision is intended to mirror.

44. **Clarity – Form, Section 6.10:** The Board proposes to add Health & Saf. Code § 1261(c) and (g) as citations for this requirement, and neither subdivision

is applicable. Subdivision (c) simply does not apply, and there is no subdivision (g).

45. **Consistency – Form, "Note" Following Section 6.21:** In mirroring a requirement in Health & Saf. Code § 1261.6(f)(7)(A), the Board omitted an important requirement. Health & Saf. Code § 1261.6(f)(7)(A) requires, in pertinent part, "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." This Note omits the provision that this applies to systems that "are not patient specific in their design".

46. **Consistency – Form, Section 6.23:** The Board did not successfully mirror language in Health & Saf. Code § 1261.6(b). Regarding a recordkeeping requirement, the statute applies to "transaction information" while the proposed regulation applies to "records of inspections completed by the pharmacist".

47. **Authority – Form, Section 6.23:** A provision requiring an assessment of whether records of inspections completed by the pharmacist are kept for at least three years cites a Department of Health Care Services (the "Department") regulation (22 CCR § 70263(f)(3)). The other citation to Health & Saf. Code § 1261.6(b) is sufficient, so the citation to the Department regulation may need to be deleted since it is not a Board regulation.

48. **Consistency – Form, Section 7.3:** In revising a provision mirroring Bus. & Prof. Code § 4187.1(a)(2), the Board proposes to change a reference from "the statewide Inmate Medical Services Policies and Procedures" to "the California Correctional Health Care Services Health Care Department Operations Manual." This is supposedly to align with a statutory change to Bus. & Prof. Code § 4187.2(b)(1), wherein a reference to the former document was replaced by a reference to the latter as a result of S.B. 118 (Ch. 29, Stats. 2020). However, the statutory provision in Bus. & Prof. Code § 4187.1(a)(2) that the Board intends to mirror still references the former document, and the Board does not explain why this change is still necessary. (NOTE: The resolution to this issue may result in the proposed addition of Bus. & Prof. Code § 4187.2 as a citation inappropriate.)

49. **Consistency – Form, Section 7.4:** This is similar to Issue #48, *supra*, except that the provision being mirrored is in Bus. & Prof. Code § 4187.1(b).

50. **Consistency – Form, Section 7.14:** An existing citation to Pen. Code § 5042.2 needs to be changed to Pen. Code § 5024.2, as this is the statute cited in the provision this section mirrors, Bus. & Prof. Code § 4187.2(b)(1).

51. **Consistency – Form, Section 7.16:** This is similar to Issue #48, *supra*, except that the provision being mirrored is in Bus. & Prof. Code § 4187.3.

52. **Clarity – Form, "Please Note" Following Section 8:** The word "uses" needs to be changed to "used" in the following sentence: "This section addresses additional requirements for hospital pharmacies and drug rooms operating an ADDS uses for dispensing."

53. **Clarity and Consistency – Form, Section 8.10:** This section requires the following assessment: "Medication guides are provided on required medications." The only citation for this requirement is 21 C.F.R. § 208.1. However, no such requirement exists in the cited federal regulation section.

54. **Clarity – Form, Section 8.11:** The phrase "black box" is used in this section, which states, "Black box warning information is in conformance with 21 C.F.R. § 201.57(c)." However, this term is not used in the cited federal regulation section, nor is it otherwise defined in the Form.

55. **Clarity – Form, Section 9.3 (Including Sections 9.3.1-9.3.4):** According to the ISR, this section requires an assessment regarding compliance with CCR § 1715.65(h). However, no such requirements exist in the cited CCR section.

56. **Clarity – Form, Introductory Paragraph Preceding Section 9.5:** A Note appears immediately before Section 9.5. According to the ISR, this Note applies to Sections 9.5 to 9.7. However, this is not stated in the Note. A slight formatting change moving the indentation of this introductory paragraph further left may resolve this issue.

57. **Clarity – Form, Introductory Paragraph Preceding Section 9.8:** The issue here is similar to Issue #56, *supra*. A Note appears immediately before Section 9.8. According to the ISR, this Note applies to Sections 9.8 to 9.12. However, this is not stated in the Note. A slight formatting change moving the indentation of this introductory paragraph further left may resolve this issue.

58. **Consistency – Form, Introductory Paragraph Preceding Section 9.8:** The Board did not successfully mirror language in Bus. & Prof. Code § 4427.65(c)(5). The scope of applicability of the statutory provision is providing pharmacy services pursuant to Bus. & Prof. Code § 4017.3 **and Art. 25 in Ch. 9 in Div. 2 of the Bus. & Prof. Code**. The proposed regulation only applies to providing pharmacy services pursuant to Bus. & Prof. Code § 4017.3 (i.e., the reference to Art. 25 is omitted).

59. **Consistency – Form, Section 9.10:** Similar to Issue #58, *supra*, the Board did not successfully mirror language in Bus. & Prof. Code § 4427.65(c)(5)(C). The scope of applicability of the statutory provision is providing services to the facility

pursuant to Art. 25 in Ch. 9 in Div. 2 of the Bus. & Prof. Code. The proposed regulation only applies to providing services to the facility (i.e., the reference to Art. 25 is omitted).

60. **Consistency – Form, Section 9.14:** A reference to "ADDS" should instead be to "AUDS". The statutory provision being mirrored (Bus. & Prof. Code § 4427.65(b)) references "the device", and the only other "device" referenced in the statutory provision is an AUDS. However, in an attempt to mirror this provision, the Board uses "ADDS" instead.

61. **Clarity – Form, Section 9.15:** As a grammatical change, the phrase "The facility and the pharmacy ***has*** developed" needs to be changed to "***have*** developed".

62. **Clarity – Form:** In numerous instances throughout the Form, the Board is adding a single checkbox next to individual self-assessments, and it is unclear how these check boxes are to be utilized.[1] In every instance, these individual self-assessments are preceded by a single, over-arching self-assessment that has three check boxes: one each for "Yes", "No", and "N/A". Presumably, the single check boxes for the individual self-assessments will only be used for affirmative responses, but the Board does not clarify this point.

63. **Clarity – Form, Certification of Completed Action Plan, Acknowledgment by Owner of the Pharmacy or Hospital Administrator Operating the ADDS, pg. 45:** The title of this certification acknowledgment was incorrectly amended to read "Acknowledgment by of the Pharmacy or Hospital Administrator Operating the ADDS" instead of "Acknowledgment by Owner of the Pharmacy or Hospital Administrator Operating the ADDS".

64. **Originally Proposed Text – Clearly Indicated Changes:** The underlying text does not match what is printed in the CCR and the most recently approved version of the Form.

65. **Originally Proposed Text – Changes Not Clearly Indicated in the Form:** The method used to indicate changes to the form in the originally proposed text was double underline for additions and double strikethrough for deletions. However, some changes were made in single underline and single strikethrough for additions and deletions, respectively.

[1] In some instances, these individual self-assessments were in outline format and accompanied by a bullet point. In other instances, they were accompanied by three check boxes: one each for "Yes", "No", and "N/A". Lastly, some of these individual self-assessments are new and therefore did not have any prior formatting.

66. **First and Second 15-Day Notices:** The Board did not list the Form in either Notice even though it was further amended in both the first and second modified regulation texts.

67. **First Modified Regulation Text – Method for Indicating Changes:** The Board's method for indicating changes in the first modified regulation text (~~*italicized double strikethrough*~~ for deletions and *italicized wavy underline* for additions) was not included in the First 15-Day Notice or the CCR portion of the First Modified Regulation Text, but only the Form 17M-112 portion of the First Modified Regulation Text. This is mostly an issue because the Form 17M-112 was not listed in the First 15-Day Notice, so it is possible that not everyone had access to the Board's method for indicating changes.

68. **First Modified Regulation Text – Clearly Indicated Changes:** Not all changes were clearly indicated.

69. **Reference:** There are two issues with statutes the Board proposes to add as References in the one affected section:

69.1. The Board proposes to add Bus. & Prof. Code § 4117.3, but no such statute exists or has ever existed.

69.2. The Board proposes to add Bus. & Prof. Code § 4119.1, but this statute was repealed by Stats. 2018, Ch. 666 (S.B. 1447) effective 1/1/2020.

70. **UID:** The Board did not discuss the following References in the one affected section that were amended after publication of the 45-Day Notice:

70.1. Bus. & Prof. Code § 4113 (amended by Stats. 2023, Ch. 470 (A.B. 1286) effective 1/1/2024);

70.2. Bus. & Prof. Code § 4119.11 (amended by Stats. 2023, Ch. 723 (S.B. 816) effective 1/1/2024); and

70.3. Bus. & Prof. Code § 4400 (amended by Stats. 2023, Ch. 723 (S.B. 816) effective 1/1/2024).

71. **FSR – IBR:** Regarding the Form, the FSR is missing the statement required by 1 CCR § 20(c)(2).

Attachment 3

Frequently Asked Questions – Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Assembly Bill 1286, which becomes effective January 1, 2024, includes several patient safety provisions. Given the encompassing nature of the measure, the Board is releasing this FAQ to assist licensees with understanding the bill. To facilitate use of this document, short titles will be used to reference the various topics.

Medication Error Reporting

1. Q: What types of licensees are required to report medication errors under AB 1286?

A: A community pharmacy licensed pursuant to Article 7 of Chapter 9 of Division 2 of the Business and Professions Code (BPC) is required to report medication errors under AB 1286. For purposes of the measure, the term "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, including both resident and nonresident pharmacies, but not including facilities of the California Department of Corrections and Rehabilitation.

[Reference: BPC 4113.1(a), (c), and (e)]

2. Q: What is considered a medication error for purposes of AB 1286 reporting?

A: For purposes of AB 1286 reporting, the term "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration, but does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

3. Q: AB 1286 requires a community pharmacy to report medication errors to an entity approved by the Board. What is the name of the approved entity?

A: The Board is in the process of identifying an entity to receive AB 1286 medication error reports. Until the Board has approved the entity, medication errors do not need to be reported under BPC 4113.1. The Board reminds licensees, however, that provisions for documenting medication errors as established in California Code of Regulations (CCR), title 16, section 1711 (relating to quality assurance programs) remain effective. AB 1286 does not impact the quality assurance documentation requirements.

[Reference: BPC 4113.1(a); 16 CCR 1711]

4. Q: Given the delay in implementation for reporting medication errors under AB 1286, how will I know when the medication error reporting becomes effective?

A: The Board will use a variety of means to announce the approval of the entity and the implementation timeframe, including through the Board's subscriber alert system and posting information on its website.

Note: As a reminder, all licensees are required to enroll in the Board's subscriber alert system. Additional information is available here.

[Reference: BPC 4013]

5. **Q: I work in an outpatient hospital pharmacy. Do AB 1286's requirements for medication error reporting apply to our pharmacy?**

A: Yes. However, pursuant to subdivision (e) of BPC 4113.1, an outpatient hospital pharmacy shall not be required to report to the Board-approved entity a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to section 1279.1 of the Health and Safety Code (HSC). The State Department of Public Health may share any such report with the Board.

[Reference: BPC 4113.1(e)]

6. **Q: I work in an outpatient hospital pharmacy. Am I required to report all medication errors to the Board-approved entity under the provisions of AB 1286?**

A: It depends. AB 1286 generally requires a community pharmacy licensed by the Board to report, either directly or through a designated third party, all medication errors to an entity approved by the Board; however, subdivision (e) of BPC 4113.1 establishes a limited exemption from the reporting requirements, and specifies that an outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to HSC 1279.1.

[Reference: BPC 4113.1]

7. **Q: If I am reporting medication errors to an entity approved by the Board, am I still required to complete a quality assurance review and report?**

A: Yes. The Board's quality assurance regulations remain in place and pharmacies are still required to comply with those regulations.

[Reference: 16 CCR 1711]

Minimum Staffing Provisions

8. **Q: What minimum staffing requirements does AB 1286 establish?**

A: Effective January 1, 2024, a chain community pharmacy subject to BPC 4113.5 is required to be staffed at all times during normal business hours (defined as 8:00 am to 7:00 pm) with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services, unless any of the following conditions apply:

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.

- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm, in which case the minimum staffing requirement does not apply during the hours before 8:00 am and after 7:00 pm.
- The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, CLIA-waived tests, or any other ancillary services provided by law, this exemption does not apply.

In addition, where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

Note: Additional minimum staffing requirements are detailed under "Pharmacy Technician Expanded Duties" below.

[Reference: BPC 4113.6]

9. Q. If a pharmacist is solely scheduled with an intern, does that meet the minimum staffing requirement established in BPC 4113.6(a)?

A: AB 1286 is silent about the impact to the minimum staff requirement when interns are present. As stated in the prior question, a pharmacist on duty may waive the BPC 4113.6(a) minimum staffing requirement during specified hours based on workload need.

[Reference: BPC 4113.6(a)]

Staffing Decisions

10. Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

11. Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Unsafe Pharmacy Conditions

12. Q: I am concerned that the working conditions of the pharmacy are harmful. What should I do?

A: Effective January 1, 2024, the pharmacist-in-charge or pharmacist on duty is required to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:

- Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

The Board recommends that the PIC or pharmacist on duty document any such notification made by them to store management. The Board also recommends that pharmacies establish policies and procedures for the notification process to ensure reporting personnel and store management have a common understanding of the process to be used.

[Reference: BPC 4113(d)]

13. Q: Is store management required to take action based on my report?

A: Yes. Effective January 1, 2024, store management is required to take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

14. Q: I made a report, but the conditions remain. What should I do?

A: Effective January 1, 2024, the law states that if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified.

[Reference: BPC 4113(d)]

15. Q: How do I make a report to the Board?

A: The Board has established a dedicated email for such reporting: — PharmacyAlert@dca.ca.gov. The Board requests that the following information be provided with the notification:

- Name and license number of pharmacy,
- Name and contact information for reporting party,
- Name and contact information for store management that received the initial notification,
- Copy of the notification provided to store management,
- Documentation of the conditions including photographs, temperature logs, etc.

[Reference: BPC 4113(d)]

16. Q: Do these requirements apply to all pharmacies?

A: No, facilities of the Department of Corrections and Rehabilitation are exempt from these requirements.

[Reference: BPC 4113(d)(6)]

Pharmacy Technician Expanded Duties

17. Q: What are the expanded duties pharmacy technicians may perform pursuant to AB 1286?

A: Effective January 1, 2024, qualified pharmacy technicians may perform the following duties under specified conditions:

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as waived under CLIA
- Receive prescription transfers
- Accept clarification on prescriptions

[Reference: BPC 4115(b)]

18. Q: What are the specified conditions that must be met for a pharmacy technician to perform the expanded duties?

A: The law establishes several conditions, as follows:

- The duties are performed under the direct supervision and control of a pharmacist.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in BPC 4115(a) (*i.e.*, packaging, manipulative, repetitive, or other nondiscretionary tasks).
- The pharmacy technician is certified pursuant to the provisions of BPC 4202(a)(4) and maintains the certification.
- The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education that includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.
- The pharmacy technician is certified in basic life support.

[Reference: BPC 4115(b)(1)]

Unprofessional Conduct

19. Q: As a pharmacist, I know I am responsible for using professional judgment when taking care of patients. I believe my employer has implemented a policy that undermines my professional judgment. Does AB 1286 address this?

A: Yes. Effective January 1, 2024, the unprofessional conduct code was amended to expand the list of specified actions that constitute unprofessional conduct to include actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with laws and regulations, or exercise professional judgment.

[Reference: BPC 4301(v) and (w)]

20. Q: If I believe the pharmacy is violating the law, how do I file a complaint with the Board?

A: A consumer or licensee may file a complaint with the Board online. Fill out the boxes on the form that apply to your complaint. The Board requests that documentation or other evidence that support your allegations be retained and provided to the Board if requested.

21. Q: Can I file a complaint anonymously?

A: Yes. The Board welcomes and investigates complaints received, including anonymous complaints. However, anonymous complaints may limit the Board's ability to investigate.

Surgical Clinic Provisions

22. Q: Under new requirements established by AB 1286, our surgical clinic is required to complete a Surgical Clinic Self-Assessment Form. Where can I find that form?

A: The Surgical Clinic Self-Assessment Form is currently being developed. Upon approval, the Board will release a subscriber alert and post the form on its website. The form will be available here.

[Reference: BPC 4192(b)]

23. Q: It is my understanding that AB 1286 makes changes to the renewal requirements for surgical clinics. Please provide me with an explanation of the changes.

A: Effective January 1, 2024, as part of the renewal process for a surgical clinic, the consulting pharmacist must certify compliance with the quarterly inspections as required by BPC 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in BPC 4192 must be provided to the Board.

[Reference: BPC 4204(c)]

24. Q: How does the consulting pharmacist certify compliance with the quarterly inspection requirements?

A: The renewal application form includes a statement that must be completed by the consulting pharmacist as part of the renewal process. As a reminder, the Board has a policy to accept digital signatures. The policy is available here.

[Reference: BPC 4192(b), 4204(c)]

25. Q: How do I submit a copy of the completed self-assessment form with our renewal application?

A: A copy of the completed self-assessment form can be mailed along with the renewal application form and renewal fee. It is recommended that licensees consider mailing the renewal application form, fee, and self-assessment form to the Board's office for handling, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

[Reference: BPC 4204(c))

Attachment 4

Board of Pharmacy

Enforcement Workload Statistics FY 2023/24

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	820	821	812	0	2,453
Closed	767	603	804	0	2,174
					Quarter Ending
Pending	1,932	2,203	2,247	0	2,247
Average Days for Investigation	215	209	243	0	243

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	745	987	1,000	0	1,000
Drug Diversion / Fraud	241	238	224	0	224
Prescription Drug Abuse	221	240	232	0	232
Compounding	40	43	45	0	45
Outsourcing	16	22	13	0	13
Probation / PRP	42	36	36	0	36
Enforcement	53	41	62	0	62
Criminal Conviction	571	594	635	0	635

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	65	56	65	0	186
Closed					
Approved	30	28	41	0	99
Denied	7	17	22	0	46
Total Closed (includes withdrawn)	***40***	***46***	***65***	***0***	***151***
					Quarter Ending
Pending	110	123	114	0	114

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	229	185	316	0	730
Non-Jurisdictional	115	105	134	0	354
No Violation	51	55	78	0	184
No Further Action	33	28	35	0	96
Other - Non-Substantiated	60	27	46	0	133
Subject Educated	21	16	35	0	72

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	47	48	43	0	138
Citations Issued	270	160	133	0	563
Proof of Abatement Requested	36	25	16	0	77
Appeals Referred to AG's Office	42	10	24	0	76
Dismissed	3	12	4	0	19
Total Fines Collected	***$702,692***	***$370,263***	***$279,988***	***$0***	***$1,352,943***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	78	64	63	0	205
Pleadings Filed	75	53	42	0	170
Total Closed *(Includes Withdrawns)*	46	57	69	0	172
Pending					Quarter Ending
Pre-Accusation	144	137	145	0	126
Post-Accusation	169	185	172	0	186
Total Pending	**313**	**322**	**317**	**0**	**312**

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	4	1	0	7
Intern Pharmacist	0	2	0	0	2
Pharmacy Technician	8	15	23	0	46
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	3	1	0	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***24***	***25***	***0***	***60***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***0***	***0***	***0***	***1***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	8	8	6	0	22
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	3	4	0	11
Designated Representative	0	0	0	0	0
Wholesaler	0	0	1	0	1
Pharmacy	2	4	3	0	9
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***14***	***15***	***14***	***0***	***43***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	2	1	3	0	6
Intern Pharmacist	0	0	1	0	1
Pharmacy Technician	1	3	5	0	9
Designated Representative	0	0	0	0	0
Wholesaler	0	0	1	0	1
Pharmacy	1	0	1	0	2
Sterile Compounding	0	1	1	0	2
Outsourcing	0	0	0	0	0
Total	***4***	***5***	***12***	***0***	***21***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	6	4	1	0	11
Intern Pharmacist	0	0	1	0	1
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	1	4	0	6
Sterile Compounding	0	0	1	0	1
Outsourcing	0	0	0	0	0
Total	***8***	***5***	***7***	***0***	***20***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	0	1	0	1
Intern Pharmacist	1	0	1	0	2
Pharmacy Technician	0	1	2	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	1	0	0	0	1
Total	***2***	***1***	***4***	***0***	***7***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	1	0	1
Outsourcing	0	0	0	0	0
Total	***1***	***1***	***1***	***0***	***3***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$361,102***	***$211,270***	***$234,328***	***$0***	***$806,699***
Cost Recovery Collected	***$254,954***	***$203,035***	***$195,444***	***$0***	***$653,433***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	1	2	2	0	5
Automatic Suspension Orders	1	1	1	0	3
Penal Code 23 Restrictions	2	6	2	0	9
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	1	0	0	1
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	164	164	163	0	163
Intern Pharmacist	2	1	2	0	2
Pharmacy Technician	20	21	24	0	24
Designated Representative	1	1	1	0	1
Wholesaler / 3PL	2	2	3	0	3
Pharmacy	52	53	52	0	52
Sterile Compounding	9	10	9	0	9
Outsourcing	0	0	0	0	0
Total	***250***	***252***	***254***	***0***	***254***
Probation Compliance Measures					Total
Probation Office Conferences	18	16	8	0	42
Probation Interviews / Site Inspections	141	117	114	0	372
Probation Terminated / Completed	25	16	14	0	55
Referred to AG for Non-Compliance	0	0	0	0	0

As of 3/31/2024

Board of Pharmacy

Citation and Fine Statistics FY 2023/24

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	24	21	15	0	60
Pharmacist-in-Charge with Fine*	13	13	7	0	33
Pharmacist no Fine	78	28	29	0	135
Pharmacist-in-Charge no Fine*	48	25	27	0	100
Pharmacy with Fine	134	87	56	0	277
Pharmacy no Fine	22	14	20	0	56
Pharmacy Technician with Fine	4	0	3	0	7
Pharmacy Technician no Fine	7	2	16	0	25
Wholesalers	0	1	2	0	3
Designated Representative	1	1	0	0	2
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	1	0	0	0	1
Hospital Pharmacy	2	2	2	0	6
Miscellaneous**	17	5	9	0	31
Unlicensed Premises	2	0	2	0	4
Unlicensed Person	0	1	0	0	1

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	17%	1716 - Variation from prescription	30%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	14%
1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	13%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge	15%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	10%
1716 - Variation from prescription	13%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	10%	4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	10%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	8%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	10%	4301 - Unprofessional Conduct…	10%
1304.11(c) - Inventory Requirements; Biennial inventory date	8%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	8%	1304.11(c) - Inventory Requirements; Biennial inventory date	10%
1751.3(a) - Sterile Compounding Policies and Procedures; Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding…	8%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in- charge shall constitute grounds for disciplinary action	7%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	10%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	8%	4301 - Unprofessional Conduct…	7%	111295 - It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.	10%
1715.65(a)(1) - Inventory Activities and Inventory Reconciliation reports... (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	8%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy	7%	1715.65(a)(1) - Inventory Activities and Inventory Reconciliation reports... (a) Every pharmacy, and every clinic licensed under section 4180 or 4190 of the Business and Professions Code, shall perform	10%
111295 - It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.	8%	4113(e) - Pharmacist-in-Charge: Notification to Board; Responsibilities; If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist	5%	1751.3(a) - Sterile Compounding Policies and Procedures; Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding…	10%
4301 - Unprofessional Conduct…	8%	1707.2 - Notice to Consumers and Duty to consult	3%	1716 - Variation from prescription	10%

California State Board of Pharmacy

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2023 through March 2024.

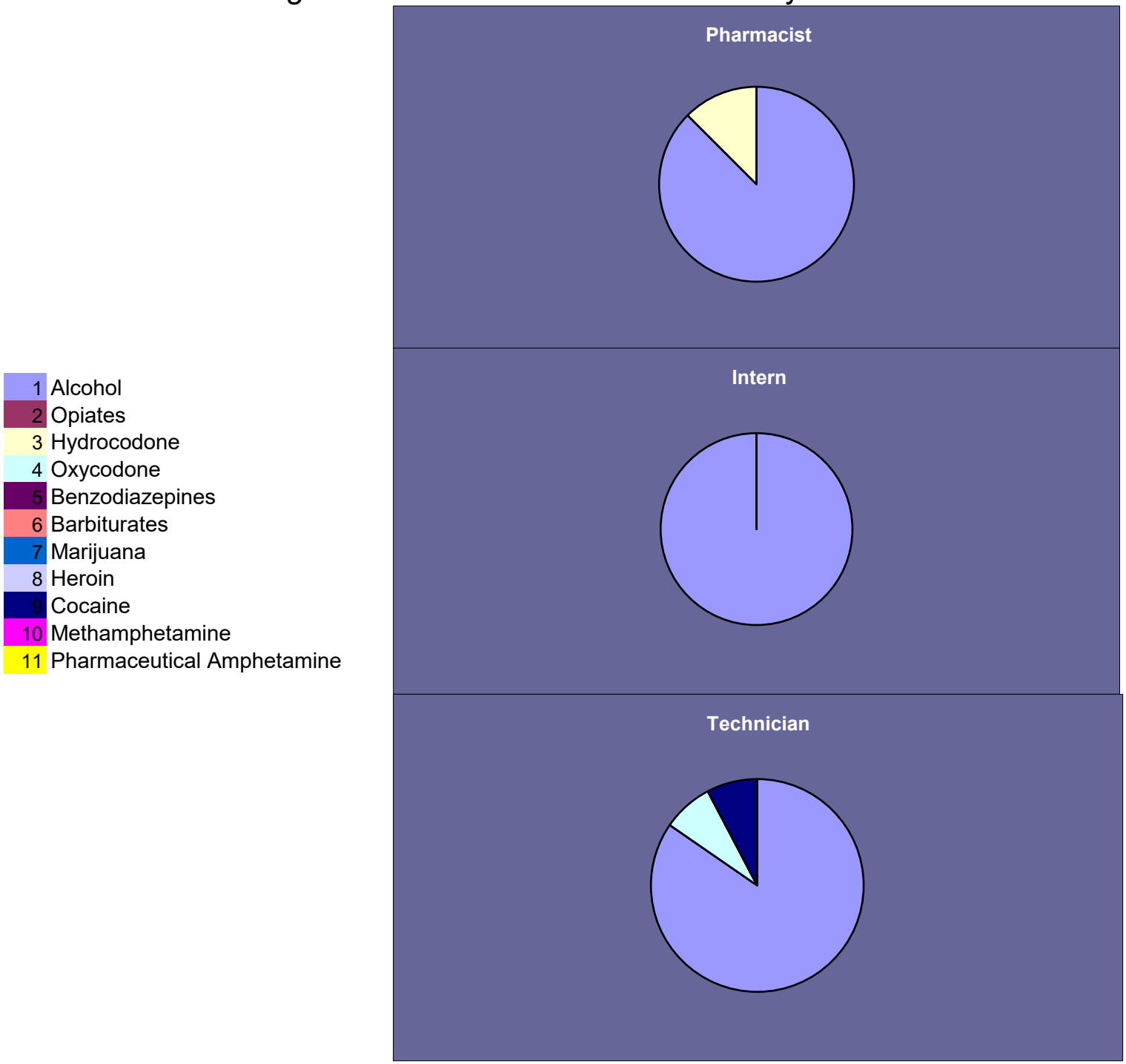
Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	23/24
PRP Intakes					
PRP Self-Referrals			2		2
PRP Probation Referrals	1	1	3		5
PRP Under Investigation	2		1		3
PRP In Lieu Of (investigation conducted)	2				2
Total Number of PRP Intakes	5	1	6		12
New Probationers					
Pharmacists		6	2		8
Intern Pharmacists	1		1		2
Pharmacy Technicians	4	4	5		13
Total New Probationers	5	10	8		23
PRP Participants and Recovery Agreements					
Total PRP Participants	28	25	28		N/A
Recovery Agreements Reviewed	23	18	24		65
Probationers and Inspections					
Total Probationers	40	44	49		N/A
Inspections Completed	20	21	24		65
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1		2		3
Drug Tests					
Drug Test Ordered (PRP and Probationers)	404	414	467		1285
Drug Tests Conducted (PRP and Probationers)	389	407	446		1242
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	3	1	2		6
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationer	7	3	10		20
Termination from PRP	2		1		3
Probationers Referred for Discipline	1		1		2
Closure					
Successful Completion (PRP and Probationers)	3		3		6
Termination (Probation)	1				1
Voluntary Surrender (Probation)	1	4	1		6
Surrender as a result of PTR (Probation)	1	1			2
Closed Public Risk (PRP)	2		1		3
Non-compliance (PRP and Probationers)	10	16	7		33
Other (PRP)	2	2	2		6
Patients Harmed					
Number of Patients Harmed (PRP and Probationers					Zero

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2023 through March 2024.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	23/24
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 23/24**
Alcohol	2	1	4		7
Ambien					
Opiates			1		1
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 23/24**
Alcohol	2		1		3
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 23/24**
Alcohol	4	2	5		11
Opiates					
Hydrocodone					
Oxycodone		1			1
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine		1			1
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2023 to March 2024



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