



## Enforcement and Compounding Committee Report April 11, 2024

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. Call to Order, Establishment of Quorum, and General Announcements**

### **II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**

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

### **III. Approval of Draft Minutes from the January 23, 2024 Enforcement and Compounding Committee Meeting**

**Attachment 1** includes a copy of the draft minutes.

### **IV. 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.

#### For Committee Consideration and Discussion

During the meeting members will receive a presentation from Andrew Funk, NABP Director of Government Affairs.

### **V. Discussion and Consideration of 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.

### For Committee Consideration and Discussion

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 will have the opportunity to review the proposed changes. Should members agree with the proposed changes, the following motion could be used to recommend initiation of the rulemaking process.

**Suggested motion:** Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1715.1 [insert either “as proposed to be amended” or “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 CCR Section 1715.1 and the updated ADDS self-assessment form.

## **VI. Discussion on 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 that are not licensed by the Board of Pharmacy, the California Department of Public Health, or any other similar agency, such as IV hydration clinics, 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 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.

#### For Committee Consideration and Discussion

During the meeting members will have the opportunity to discuss the issue and determine what, if any, action may be appropriate for the Board to consider. To assist with the discussion the following policy questions may be helpful.

1. Does the Committee believe the Board should have a role in regulation of IV hydration clinics?
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?
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](#)?
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?

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 s to such businesses?
6. Does the Committee believe the Board should release a policy statement encouraging compliance with federal law and compliance with USP?
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?

## **VII. Discussion and Consideration of 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.

### For Committee Consideration and Discussion

During the meeting members will have the opportunity to review the additional FAQs and provide feedback to staff. After discussion, should the Committee believe the FAQs are ready for consideration and approval by the Board, the following motion may be appropriate.

**Motion:** Recommend approval of the additional FAQs related to Assembly Bill 1286.

**Attachment 3** includes a copy of the draft FAQs.

## **VIII. Discussion and Consideration of Enforcement Statistics**

During the first eight months of the fiscal year, the Board received 2,208 complaints and closed 1,798 investigations. The Board has issued 119 letters of admonishment, 521 citations and referred 175 cases to the Office of the Attorney General. The Board has revoked 56 licenses, accepted the disciplinary surrender of 20 licenses, formally denied

three applications, and imposed other levels of discipline against 58 licensees and/or applicants.

As of March 1, 2024, the Board had 1,662 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Apr. 1, 2023		Jul. 1, 2023		Oct. 1, 2023		Jan. 1, 2024		Mar. 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	107	7
Cases Under Investigation	874	138	942	141	982	138	1037	146	1061	134
Pending Supervisor Review	146	22	164	31	183	47	286	77	355	85
Pending Second Level Review	245	36	79	22	82	22	81	21	115	26
Awaiting Final Closure	8	43	148	12	34	13	26	19	24	3

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

**IX. Future Committee Meeting Dates**

- July 17, 2024
- October 16, 2024

**X. Adjournment**

# **Attachment 1**



**California State Board of Pharmacy**  
2720 Gateway Oaks Drive, Suite 100  
Sacramento, CA 95833  
Phone: (916) 518-3100 Fax: (916) 574-8618  
www.pharmacy.ca.gov

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



**California State Board of Pharmacy**  
**Department of Consumer Affairs**  
**DRAFT Enforcement and Compounding Committee Meeting Minutes**

**Date:** January 23, 2024

**Location:** OBSERVATION AND PUBLIC COMMENT IN PERSON:  
California State Board of Pharmacy  
2720 Gateway Oaks Drive, First Floor Hearing Room  
Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM  
REMOTE LOCATIONS VIA WEBEX

**Board Members**

**Present:** Maria Serpa, PharmD, Licensee Member, Chair  
Renee Barker, PharmD, Licensee Member, Vice Chair  
Indira Cameron-Banks, Public Member  
Seung Oh, PharmD, Licensee Member  
Nicole Thibeau, PharmD, Licensee Member

**Staff Present:** Anne Sodergren, Executive Officer  
Julie Ansel, Assistant Executive Officer  
Corinne Gartner, DCA Counsel  
Debbie Damoth, Executive Specialist Manager

**I. Call to Order, Establishment of Quorum, and General Announcements**

Chairperson Serpa called the meeting to order at approximately 9:01 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.



## II. **Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**

Members of the public in Sacramento were provided the opportunity to comment.

A representative from Pharmapod requested the opportunity to present their platform to the Committee at a future meeting.

Members of the public were provided the opportunity to comment via WebEx.

A representative of Sutter Health requested that the Committee provide an article in *The Script* or a list of frequently asked questions (FAQs) regarding compounding standards. The representative stated there was confusion based on the statement on the Board's website if facilities could move forward fully with USP standards or if facilities must also abide by the current California regulations.

A representative from the PSO Alliance for the Patient Medication Safety requested to make a presentation to the Board at a later date.

A consulting pharmacist with ambulatory surgery centers asked about the Board's involvement with ambulatory surgery centers, noting issues that have been seen related to controlled substance storage, management, and records. The consulting pharmacist asked if there was a possibility of the Board to regulate the environment and asked the Board for assistance, noting it was a large issue.

Chairperson Serpa encouraged the consulting pharmacist to use the Ask an Inspector service provided by the Board of Pharmacy.

A pharmacist was following up on a request they made at the last full Board meeting for FAQs regarding adding flavoring agents. The pharmacist requested that this be added as a future agenda item. The pharmacist asked the Board keep in mind California specific laws, particularly Business and Professions Code (BPC) section 4052.5, which allows the pharmacist to make changes in the form of the medication without necessarily contacting the prescriber. Dr. Serpa directed the pharmacist to the Board's alerts sent out to answer the question.

Chairperson Serpa noted many comments received were for current agenda topics. Dr. Serpa added there were also members of the public interested in the contracting process for the entity for medication errors that would also be discussed in a future agenda item.

Members were provided the opportunity to add agenda items to a future agenda.

Member Thibeau expressed interest in hearing presentations from commenters about the entity for medication errors or to make sure they have the opportunity to be a part of the process. Dr. Serpa noted the contracting process would be discussed later on the agenda.

**III. Discussion, Consideration, and Approval of Draft Minutes from the October 19, 2023 Enforcement and Compounding Committee Meeting**

The October 19, 2023 Enforcement and Compounding Committee meeting minutes were presented for review and approval.

Members were provided the opportunity to comment; however, no comments were made.

**Motion:** Approve the October 19, 2023 Enforcement and Compounding Committee meeting minutes as presented.

**M/S:** Oh/Barker

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

**Support: 5 Oppose: 0 Abstain: 0 Not Present: 0**

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

**IV. Presentation on the Canadian Medication Incident Reporting and Prevention System (CMIRPS) by ISMP Canada.**

Chairperson Serpa recalled during the October 2023 meeting as part of the Committee's implementation discussion for Assembly Bill 1286, the Committee decided it was appropriate to receive presentations from entities that currently receive and review medication errors. Dr. Serpa introduced and welcome Enna Aujla, Sylvia Hyland, Melissa Sheldrick, and Carolyn Hoffman from ISMP Canada.

Ms. Hoffman introduced her team. Ms. Sheldrick shared how medication errors impacted her life by the death of her young son due to medication errors. Ms. Hoffman reviewed the medication incidents and ISMP Canada's Unique Mandate. Ms. Hyland presented on the reporting, learning, and acting on medication incidents. Ms. Sheldrick discussed how each pharmacy contributes their incident data. Ms. Aujla presented provincial and national shared learning improvements. Ms. Hoffman, Ms. Aujla, Ms. Sheldrick, and Ms. Hyland continued with explaining data analysis and shared learning practice supports with ISMP Canada.

Members were provided the opportunity to comment.

Member Barker asked about the need to increase diversity and inclusivity in its activities. Ms. Sheldrick provided an update on the processes being updated to address increased diversity and inclusivity for all Canadians.

President Oh thanked ISMP Canada representatives for their time.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A representative of CCAP asked what the fees were for processing. Ms. Aujla provided the annual cost of \$70 plus tax and another fee to the platform provider specific to the platform provider.

A pharmacist asked if there were other reporting programs in Canada. Ms. Hoffman provided there were other programs based on facility type. Ms. Sheldrick added consumers also provide reports on errors.

A pharmacist commented about a concern regarding access to the error reporting database (e.g., by media, attorneys, etc.) and asked about the protection of the data as a way of encouraging reporting of the data. Ms. Hoffman provided that the error reporting information submitted was anonymous and not patient/case specific. Ms. Hoffman noted there were clear policies and procedures in place to protect privacy as well as data sharing agreements. Ms. Hoffman noted that this had never been an issue. Ms. Hyland confirmed the data is anonymous and de-identified. Ms. Hoffman noted the different types of legal systems in Canada and the United States.

Members were provided the opportunity to comment after public comment was received. However, no comments were made.

Chairperson Serpa thanked the ISMP Canada representatives for their presentation and time.

**V. Presentation on Medication Error Reporting by the Agency for Healthcare Research and Quality**

Chairperson Serpa advised the Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency charged with improving the safety and quality of healthcare nationally. The agency manages the Network of Patient Safety Databases (NPSD) that contains information voluntarily submitted by patient safety organizations.

Chairperson Serpa welcomed and introduced Andrea Timaskenka, Director of the Patient Safety Organization Division at the US Department of Health and Human Services, to provide a presentation to the Board on the development of the NPSD.

Ms. Timaskenka reviewed the most relevant authorities for the PSO program including the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and originating idea of the PSQIA legislation. Ms. Timaskenka explained PSQIA as a national learning system.

Ms. Timaskenka described the functions of the AHRQ's PSO Programs including the implementation of PSQIA and the legal protections included under the PSQIA as well as what was not protected under the PSQIA. She further explained who works with PSOs and the value added when hospitals work with PSOs. Ms. Timaskenka reviewed common formats used in multiple types of facilities.

Ms. Timaskenka also reviewed the national data systems related to the PSO programs, NPSD, and NPSD dashboards.

Members were provided the opportunity to comment.

President Oh thanked Ms. Timaskenka for her presentation and time.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx; however, no comments were made.

The Committee took a break from 10:43 a.m. to 11:00 a.m. After break, roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

## **VI. Presentation on the State Contracting Process by the California Department of Consumer Affairs**

Chairperson Serpa advised the Board received requests from a number of entities interested in serving as the entity to receive medication error reports under new BPC section 4113.1. Dr. Serpa provided a representative from the Department of Consumer Affairs would provide an overview of the request for proposal process for interested entities to understand the process. Dr. Serpa believed the presentation would also help inform the Committee about necessary information that will be required by the Board as part of the process. Dr. Serpa welcomed and introduced Miriam Lopez, Staff Services Manager II, from the Department of Consumer Affairs Business Services Office.

Ms. Lopez provided an overview of the Request for Proposal (RFP) process together with the six phases of the process including the request, RFP review, advertisement period, RFP evaluation/award, contract preparation and approvals, and contract distribution.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx; however, no comments were made.

**VII. Discussion and Consideration of Scope of Work and Contract Requirements for Inclusion in the Invitation for Bid for Interested Parties Seeking to Serve as the Approved Entity under Business and Professions Code Section 4113.1**

Chairperson Serpa provided the Committee would now review policy questions to assist in the discussion on contract requirements.

- 1. Does the Committee wish to provide feedback on the required elements of the medication error reports? Board staff recommend that at a minimum the following elements be included in error reporting.<sup>1</sup>**
  - a. Pharmacy Unique Identifier (Unique Identifier to be established by the contracted vendor)**
  - b. Type of Pharmacy (drop down menu)**
  - c. Date of incident**
  - d. Type of event (drop down menu)**
  - e. Stage of process where error occurred (drop down menu)**
  - f. Type of patient (drop down menu)**
  - g. Age of patient (drop down menu)**
  - h. Sex**
  - i. Patient harm (drop down menu)**
  - j. Type of staff involved (drop down menu, may select more than one)**
  - k. Staffing at the time the event occurred or on the date the incident occurred**
  - l. Volume of work on the date of the incident (fill-in specified number, e.g., number of new prescriptions, number of refill prescriptions, number of vaccines administered, etc.)**
  - m. Was technology involved (yes/no, if yes, brief description)**
  - n. Medication involved (narrative, drug name, strength and quantity prescribed)**
  - o. Prescription Details (e.g., e-prescribed, faxed, written, transferred, etc. (drop down menu)**

---

<sup>1</sup> Staff note that the community pharmacy common format established by AHRQ provides the foundation for many of the recommendations offered.

- p. Prescriber type (drop down menu)**
- q. Contributing factors (narrative)**
- r. Report date**

Dr. Serpa explained the first policy question for consideration was to provide feedback on the staff's recommendations for required elements of the medication error reports. Dr. Serpa noted that the staff recommendations were similar to the elements included in the common format used by AHRQ's Network of Patient Safety Databases and that she was comfortable with the recommended elements. Dr. Serpa believed the recommended elements would provide a framework to allow for the Board to gain insight into the frequency and types of medication errors and contributing factors.

Members were provided the opportunity to comment.

Member Thibeau asked what element "F" labeled as "Type of patient" means. Dr. Thibeau also asked if element "H" labeled as "Sex" meant sex assigned at birth or gender identity, noting they should be separated if required but was not sure if they were relevant.

Dr. Serpa noted element "H" was not a drop-down menu so that it wouldn't appear to be limited. Dr. Serpa added there were some medications provided to pregnant women that maybe useful data points but would be interested to know the best method to collect the information. Ms. Sodergren thought they were data points to provide additional context to the error but could reach out to AHRQ for clarification. Dr. Thibeau agreed it would be important to know for a person of childbearing potential; a transman who was pregnant; or if testosterone dose was received for a transgender medicine versus a cisgender male receiving testosterone.

Member Barker agreed with Dr. Thibeau about element "H." Dr. Barker added the error reporting system used at her workplace had more patient identifiers which might be helpful (e.g., race, culture, ethnicity, spoken language, ethnic background, written language, language barriers, etc.) to capture who was experiencing the errors. Dr. Barker commented on element "M" regarding "Was technology involved (Yes/No, if yes, brief description)" asking if there could be a drop-down menu as there were many sources of technology used that could be the source of an error.

Member Oh commented about elements “H” and “M” noting for technology a description could be added and more drop-down options (e.g., ADDS, counting machine, etc.).

Dr. Serpa expressed concern about the required elements being in place for many years based on the contracting process and requested if drop-down menus were added, a field for “other” could be included. Dr. Serpa asked if “gender” was more appropriate than “sex” but was not sure which term was appropriate. Dr. Serpa agreed with the concept of adding language barriers.

Dr. Barker thought for element “M” there could be categories listed (e.g., IV workflow manager, ADDS, etc.). Dr. Serpa would work with staff to bring something to the Board meeting that would be a little more descriptive. Dr. Thibeau agreed with collecting data on race and ethnicity to look for discrepancies and see if implicit bias was part of the medication error.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A medication safety officer agreed with the discussion by the Committee on the elements on sex, gender, and technology.

A pharmacist manager for the Walgreens Pharmacy Affairs team commented Walgreens already participates in PSOs who are listed by AHRQ. The PSOs already have codified standards for reporting quality events and the minimum elements suggested to be included in error reporting and go beyond what is utilized by the AHRQ. Walgreens suggested the Committee not recommend the suggested minimum elements to be included but that the AHRQ, PSOs and outlets determine elements to be included based on tasks completed and to avoid redundancy.

A representative from CPhA cautioned the Board from creating any extra elements beyond those currently used to avoid redundancy. The representative cited a similar example how all vaccine data must be reported to CAIR and added elements were added that caused a lot of issues with vaccine providers.



A pharmacist representative from Kaiser asked for the purpose of requiring a submission for pharmacy identifier or pharmacy identification code as neither ISMP Canada nor AHRQ collect that information. The representative expressed concern for collecting this information that could be misused.

A representative from a compounding pharmacy that compounds intrathecal drugs that are shipped directly to prescribers indicated it would be difficult to collect information like race and sex as that information does not come from prescribers.

A representative of CCAP agreed with all previous speakers.

A pharmacist commented certain items not listed were important to be collected (e.g., work hours of personnel involved, type of pharmacy, intended or received patient, patient consultation required, pharmacist/pharmacy technician impairment, etc.). The pharmacist commented the pharmacy identifier was not needed.

Members were provided the opportunity to comment after public comment was received.

Dr. Serpa recommended considering the data elements in two groups: data elements that were similar to AHRQ and data elements that were added to supplement AHRQ. Elements that would be added need to be considered at a higher level as they represent information not currently being collected.

Dr. Oh commented in understanding the sentiment and reason to add some elements but that the intent of the legislation was to have data collected and didn't want anything to hinder the collection of data. Dr. Oh thought it would be best to keep the elements as simple as possible to match AHRQ to streamline as much as possible. Dr. Oh suggested taking the comments collected at the meeting and considering amending the quality assurance regulations once approved.

Dr. Thibeau suggested added "if known" option so that if the data is available it could be collected.

**2. Does the Committee agree that the entity will provide a process or processes to collect data from all required reporters and will report, summarize, and evaluate data to provide recommendations?**

Dr. Serpa believed it was important to have a single entity be responsible for the end-to-end process, from medication error collection through evaluation, and development of recommendations that can be used to inform pharmacists and pharmacies of practice changes to reduce errors.

Members were provided the opportunity to comment.

Dr. Oh agreed with Dr. Serpa.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A representative of Pharmacy Affairs for Walgreens encouraged the Board to ensure none of the processes violate any elements of the Patient Safety and Quality Improvement Act (PSQIA) and reporting entities were able to access reports so that analysis and improvements can be made.

A pharmacist agreed with Chairperson Serpa that it should be a requirement to get the information back for the Board to know what is causing errors, priorities, and what regulations should be changed. The pharmacist noted if the contractor will send information back to the entities, there will need to be an entity identifier.

A representative of the Alliance for Quality Improvement and Patient Safety (AQIPS) suggested if there were recommendations, the recommendations should go to everyone to allow for learning. PSOs were required to provide individual feedback to individual providers. The pharmacy identifier wouldn't be necessary and it would be cost prohibitive to provide individual feedback as well as duplicative of the Patient Safety Act.

Chairperson Serpa reminded members that cameras needed to remain on or announce that technical difficulties were preventing the cameras from being on.

**3. Does the Committee wish to specify the frequency within which data is provided to the Board (e.g., quarterly, semi-annually, annually, upon request, etc.)?**

Chairperson Serpa thought at least for the first year, there may be value in requesting quarterly reporting and that the frequency might later be able to be changed to semi-annually. Dr. Serpa also thought there was a need to be able to request data on an ad hoc basis.

Members were provided the opportunity to comment.

Dr. Oh agreed with quarterly at a minimum.

Members of the public in Sacramento and via WebEx were provided the opportunity to provide comments; however, no comments were made.

**4. How frequently does the Committee prefer the entity to provide summary reports on its findings regarding trends that may be published and disseminated?**

Chairperson Serpa believed summary information should be developed and released at least semi-annually, especially at the beginning as collection of the data begins.

Members were provided the opportunity to comment.

Dr. Thibeau agreed with Dr. Serpa.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented sometimes errors require immediate response because of the serious nature of the error. The pharmacist commented there needed to be a provision in the contract that if the entity identifies something serious, the Board will be notified immediately and recommended it be included in the scope of work.

Members were provided the opportunity to comment after having received public comment.

Dr. Barker was not clear on who the information is disseminated to – does this include the consuming public. Ms. Sodergren provided the vendor would

make it available to the Board and the Board could disseminate through the Board's website and subscriber alert system.

**5. How frequently does the Committee prefer the entity to develop and disseminate information gained from the reporting to improve patient safety such as recommendations or best practices?**

Chairperson Serpa believed in some instances annual release might be sufficient but there could be certain kinds of errors that warrant a more immediate action. Dr. Serpa thought minimum frequencies should be established but then also consider requirements for release of information such as safety alerts when an error(s) reported reveal a significant risk to patients that must be addressed more quickly.

Members were provided the opportunity to comment.

Dr. Thibeau agreed on establishing a minimum and being able to send more frequently as needed. Dr. Thibeau thought maybe sending it out with *The Script* might be helpful but supported an annual minimum with more frequently releases available.

Dr. Serpa clarified this question addressed recommendations and best practices including the evaluation. Dr. Serpa thought the data would be wanted more frequently and the evaluation of the data less frequently with a minimum developed. Dr. Thibeau agreed.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A representative from AQIPS commented the law allowed the pharmacies to report through a component PSO or other agents where PSOs work with the pharmacies to implement best practices. The representative recommended not overlooking PSOs that report to the vendor.

**6. Are there certain types of events (e.g., patient death) that the Committee believes should be identified immediately and released as a safety alert within a specified timeframe?**

Dr. Serpa believed there was the potential for some issues to occur that require more immediate release of information. Dr. Serpa suggested when such an issue is identified, dissemination should be possible within a number of days of identification. She believed it was important to provide sufficient time for experts to evaluate and make recommendations that do not create new risks or have unintended consequences.

Members were provided the opportunity to comment.

Member Barker wanted to see a requirement for an immediate release for a safety alert on a quick turnaround. Dr. Serpa expressed the need to convey immediate release using a flexible standard as without imposing a deadline that might have unintended consequences.

Members of the public in Sacramento and via WebEx were provided the opportunity to provide comment; however, no comments were made.

**7. How will ad hoc or custom reports be requested if further information is desired by the Board?**

Dr. Serpa noted in addition to predetermined reports there was value in ensuring the Board could request ad hoc reports.

Members were provided the opportunity to provide comment; however, no comments were made.

Members of the public in Sacramento and WebEx were provided the opportunity to provide comment; however, no comments were made.

**8. Does the Committee wish to delegate a member to serve on the panel responsible for reviewing the proposals and selecting the vendor?**

Dr. Serpa noted staff were asking if the Committee wished to appoint a member of the Committee to serve on the panel responsible for reviewing the proposals and selecting the vendor. Dr. Serpa indicated that she would be happy to serve as the delegate if the Committee was comfortable.

Members were provided the opportunity to comment.

Members Thibeau and Barker expressed support for Dr. Serpa serving on the panel.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A representative of AQIPS commented it was a great idea to have a Board member participate in the process but was concerned only two presentations were heard by the Committee. The commenter thought others should be allowed to make presentations as well.

Dr. Serpa clarified that the presentations heard by the Committee today from ISMP and ARHQ were to provide background information to the Committee.. All organizations interested in bidding on the contract will be given the opportunity to participate through the RFP process.

A pharmacist medication safety officer suggested a flowchart or timeline to supplement the presentation provided by DCA regarding the RFP process. The pharmacist asked if possible to consider PSOs currently being used as well as exemptions.

A commenter agreed with the medication safety officer noting the commenter worked with independent and regional chain pharmacies. The commenter expressed concern if another reporting entity was required, it would be extra workload during a time when workload was trying to be reduced.

**9. As the contract will be fully funded through licensees reporting to the entity, does the Committee believe the cost to be assessed to each pharmacy reporting should be a factor in determining the entity to receive the award of the bid?**

Dr. Serpa strongly believed this should be a factor.

Members were provided the opportunity to comment.

Dr. Baker and Dr. Oh agreed with Dr. Serpa that the cost should be a factor in determining the entity to be awarded the contract.

Members of the public in Sacramento were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented about the cost for the entity and added there should be some latitude or necessity to apportion the cost based on the size of the reporting organization.

**10. Does the Committee believe the entity needs to provide a variety of means for pharmacies (or their agents) to submit the data reports (e.g., through a portal, emailing a datafile, 3<sup>rd</sup> party such as a PSO, etc.)?**

Dr. Serpa stated that she personally believed more than one option for submission was necessary. Dr. Serpa noted while some pharmacies may have staff that manage their IT systems, other may have more limited systems. Dr. Serpa believed the Committee needed to ensure that implementation is easily achievable and flexibility in the submission of reports is crucial.

Members were provided an opportunity to comment.

Dr. Oh agreed that flexibility was crucial for successful implementation of this bill.

Members of the public in Sacramento were provided the opportunity to provide comment.

A representative of Pharmapod commented in appreciation for consideration for different ways for pharmacies to report. The representative added PSOs allow for a way to reduce duplication.

Members of the public were provided the opportunity to comment via WebEx.

A representative of AQIPS commented it was important to encourage the use of PSOs. PSOs currently do this under the Patient Safety Act and are required to provide individual feedback to help pharmacies solve their own problems. The representative encouraged the use of PSOs and not providing an “either/or” scenario that might hurt the learning system.

A pharmacist commented in support of this concept noting there needed to be multiple ways for pharmacies to report and the cost must be affordable.

Dr. Serpa thanked the Committee and attendees for their time, adding if the Board agreed to delegate authority for her to work on the panel, she would use the information and discussion today when working with staff.

The Committee took a lunch break from 12:30 p.m. to 1:15 p.m. Roll call was taken. The following members were present by WebEx: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

**VIII. Discussion and Consideration of Draft Frequently Asked Questions related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)**

Dr. Serpa recalled as part of discussion on implementation of Assembly Bill 1286, the Committee determined that, due to the comprehensive nature of the measure, development of frequently asked questions was appropriate. Dr. Serpa reviewed the draft FAQs prepared by staff that covered the various provisions within AB 1286 and stated that she believed they were comprehensive and appropriate.

Members were provided the opportunity to comment.

Dr. Thibeau spoke in support of the FAQs and thought they were great.

Dr. Oh confirmed question number one was to include all pharmacies.

**Motion:** Recommend approval of the FAQs related to Assembly Bill 1286

**M/S:** Thibeau/Oh

Members of the public were provided the opportunity to comment in Sacramento; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist recommended in FAQ#1 to reference the code section in the body of the answer. The commenter recommended adding examples of



changes allowed by law in FAQ#2, FAQ#9, and FAQ#10. The commenter asked if FAQ#11 included staffing. The commenter recommended clarifying FAQ#15 applied to hospitals or other pharmacies. The commenter also recommended clarifying what FAQ#16 meant by transfers.

A medication safety officer commented about FAQ#5 and FAQ#6 that generally speaking individual errors were only reported to the Department of Public Health (DPH) if they are required to be reported due to the severity or nature of the event, noting routine medication errors were not necessarily individually reported but were part of the comprehensive medication error reduction plan (MERP) overseen by DPH. The commenter requested further clarification if hospital outpatient pharmacies were exempt.

A consultant pharmacist specializing in surgical clinics asked regarding FAQ#23 if the consultant pharmacist was able to submit a certification piece of paper signed by the consultant pharmacists with the wording of the renewal to be submitted with the renewal form. The commenter was told by Ask an Inspector that was not acceptable.

Dr. Serpa recalled a discussion about adding examples could be a potential legal issue. Counsel Gartner added FAQs can only restate the law and can't interpret or further clarify existing law. Ms. Gartner recommended not providing examples.

**Support: 5   Oppose: 0   Abstain: 0   Not Present: 0**

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

**IX. Discussion and Consideration of Proposed Revisions to Frequently Asked Questions Regarding the Use of Mobile Units**

Dr. Serpa recalled with the amendment to the statutory provisions regarding mobile units included in Assembly Bill 663, the Board needed to update the frequently asked questions to reflect the changes. Dr. Serpa reviewed and believed to be appropriate the draft revisions of FAQs prepared by staff.

Members were provided the opportunity to comment; however, no comments were made.

**Motion:** Recommend approval of the FAQs related mobile units

**M/S:** Oh/Thibeau

Members of the public were provided the opportunity to comment in Sacramento; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented that there was an example provided in FAQ#1 that was in conflict with previous information provided that examples couldn't be provided in FAQs.

A pharmacist representative of Sutter Health expressed confusion by the term "end of the day" in FAQ#8.

Members were provided the opportunity to comment after having received public comment.

Dr. Serpa inquired about the comment provided regarding FAQ#1, stating she did not think it was an example. Counsel Gartner agreed with Dr. Serpa, stating that she respectfully disagreed with the commenter that an example was provided in FAQ#1.

Dr. Serpa asked the Committee if they would like to clarify FAQ#8. Members agreed in concept with updating the language to clarify.

**Revised**

**Motion:** Recommend approval of the FAQs regarding mobile units with amendments to FAQ#8 consistent with Committee discussion.

**M/S:** Oh/Thibeau

Members of the public were provided the opportunity to comment in Sacramento and WebEx; however, no comments were made.

**Support: 5    Oppose: 0    Abstain: 0    Not Present: 0**

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

**X. Discussion and Consideration of Draft Self-Assessment Form for Surgical Clinics**

Dr. Serpa provided another part of the implementation for Assembly Bill 1286 related to the establishment of a self-assessment process for surgical clinics and referenced the draft self-assessment form for consideration in the meeting materials. Dr. Serpa thanked staff and counsel for their work on the draft. Dr. Serpa explained that because the self-assessment process for surgical clinics was established in statute versus regulation, the Board will not need to incorporate the form by reference in regulation and the approval process will be streamlined. Dr. Serpa added if members were comfortable with the provisions contained in the form, she could work with staff to finalize it.

Members were provided the opportunity to comment; however, no comments were made.

**Motion:** Recommend approval of the draft surgical clinic self-assessment form

**M/S:** Oh/Barker

Members of the public were provided the opportunity to comment in Sacramento; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist consultant specializing in surgical clinics commented all surgical clinics should be registered through the Board of Pharmacy. The pharmacist reviewed the self-assessment form in detail. The commenter

added there was no way to pre-submit the comments requesting that be added in the future. The pharmacist asked how the form should be completed if the clinic represented two of the types of clinics represented on the form. The commenter requested clarification if clinics can purchase from retail pharmacies. The commenter asked if the wholesaler provides DSQCA information on the website are the clinics required to have on paper. The commenter stated the prescriber requirements were roles outside of the surgical clinics' scope but to the prescribers who are not the employees of surgical clinics and recommended removing 5.7, 5.8, and 5.9. The wording in the self-assessment for consultant pharmacist inventory review differs from the law. The commenter recommended changing "pharmacy" to "surgical clinic" in 7.8. Additional lines needed to be provided in section 8.

A pharmacist representative from Sutter Health commented on the word "handles" in 8.5 and questioned how this would be interpreted.

Dr. Serpa reiterated the self-assessment was to re-state current law and no additional information was to be provided. Dr. Serpa thought sections 5.7, 5.8, and 5.9 were appropriate but public comment indicated otherwise. Ms. Sodergren believed inclusion was appropriate as it was vetted with the counsel prior to the meeting and would be happy to ask counsel to review the three items. Dr. Serpa believed 6.6 should be checked for agreement with the law. Dr. Serpa said additional lines could be added to 8.2. Ms. Sodergren, Dr. Oh, and Dr. Barker recommended additional pages could be added. Dr. Serpa noted the title of USP 800 contained the word "handling."

Members were provided the opportunity to comment having received public comment; however, no comments were made.

**Revised**

**Motion:** Recommend approval of the draft surgical clinic self-assessment form and delegate to the Committee chair to finalize the form with staff and counsel prior to presenting to the Board for final approval.

**M/S:** Oh/Barker

Members of the public were provided the opportunity to comment in Sacramento; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist consultant for surgical clinics asked when the next draft form would be available for review.

A pharmacist commented 5.7 was related to the ability to be licensed by the Board to buy drug stock as an entity while other prescribers can be employed by the clinic for 5.9. The pharmacists thought they were appropriate for inclusion in the self-assessment form.

**Support: 5    Oppose: 0    Abstain: 0    Not Present: 0**

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

**XI. Discussion, Consideration, and Possible Action on Self-Assessment Forms 17M-13, 17M-14, and 17M-26**

**a. Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13 (Cal. Code Regs., tit. 16, § 1715(c))**

**b. Hospital Pharmacy Self-Assessment Form 17M-14 (Cal. Code Regs., tit. 16, § 1715(c))**

**c. Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26 (Cal. Code Regs., tit. 16, § 1784(c))**

Dr. Serpa recalled in February 2023, the Board voted to update the community pharmacy, hospital pharmacy, and wholesaler/third party logistics provider self-assessment forms through a streamlined section 100 regulation process. At that time, the Board believed that given the forms restate law and do not create requirements not already established in statute and regulation, such an approach was possible. Regrettably, the Board was recently advised by the Office of Administrative Law that it could not use the streamlined process. Dr. Serpa continued that for the Committee's review today were updated versions of the three forms. As the forms do not create laws, rather restate law, Dr. Serpa believed the focus could be on the approval of the forms to the provisions that were incorporated. Dr. Serpa reviewed all three forms and believed they were

appropriate.

Members were provided the opportunity to comment; however, no comments were made.

Member Thibeau left the meeting at 1:59 p.m.

**Motion:** Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, sections 1715 and 1784 as proposed to be amended and self-assessment forms 17M-13, 17M-14, and 17M-26 incorporated by reference. Authorize the executive officer to further refine the language consistent with the Committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

**M/S:** Oh/Barker

Members of the public were provided the opportunity to comment in Sacramento; however, no comments were made.

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist representative of Kaiser commented about the community pharmacy self-assessment at 6.14 and the hospital pharmacy self-assessment at 7.11 restating the pharmacist's professional continuing education requirement as well as community pharmacy self-assessment at 9.9 and hospital pharmacy self-assessment at 10.12 restating the pharmacy technician continuing education requirement on cultural competency. The representative encouraged the Committee to think how restating the requirement would help the pharmacist-in-charge (PIC) of the pharmacy and consider removing these items from the self-assessments. The representative added the PIC shouldn't be validating this requirement.

Members were provided the opportunity to comment after having received public comment; however, no comments were made.

**Support: 4   Oppose: 0   Abstain: 0   Not Present: 1**

<b>Board Member</b>	<b>Vote</b>
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Not Present

**XII. Discussion and Consideration of Enforcement Statistics**

Chairperson Serpa referred to meeting materials that included a summary of enforcement statistics for the first six months of the fiscal year. The Board received 1,639 complaints and closed 1,371 investigations. The Board revoked 35 licenses, accepted the disciplinary surrender of nine licenses, formally denied two applications, and imposed other levels of discipline against 33 licensees and/or applicants. As of January 1, 2024, the Board had 1,582 field investigations pending. The materials provided a breakdown of the average timeframe for the various stages of the field investigation process.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

**XIII. Future Committee Meeting Dates**

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for April 11, 2024. Dr. Serpa asked that stakeholders monitor the Board's website for updates.

**XIV. Adjournment**

The meeting adjourned at 2:07 p.m.

# **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 12/1823) 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 compliance with 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.



**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 AUDDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the AUDDS. 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 Expiration Date: \_\_\_\_\_ DEA Inventory Date: \_\_\_\_\_  
Last ~~62~~ 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 States Code. [BPC 4119.11(a) ~~(a)(11)~~]
  
- 2.2 Provides pharmacy services through an ~~APDS~~**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 ~~APDS~~**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 AUDDS operated under these provisions is required.

- 2.10 An AUDDS 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 AUDDS 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: ~~==~~ADDSDS
  - APDS adjacent to the secured pharmacy area ~~(or)~~
  - APDS located in a Medical Offices
  - 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: ~~==~~ADDSDS 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: ~~ADDSDS~~ operated by a correctional clinic pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).
- SECTION ~~9~~8:
  - Hospital Pharmacy: AUDDS used for dispensing pursuant to BPC 4068 ~~(when the hospital pharmacy is closed and no pharmacist is available).~~
  - Drug Room: AUDDS used for dispensing pursuant to BPC 4056.
- SECTION 9:
  - AUDDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)
  - AUDDS 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

- 4.98 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)]~~

- 4.913 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

- 4.1014 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 an ~~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)]~~

4.1~~8~~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.

4.2~~0~~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)]



- ~~4.2014.1.~~ 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)]
- ~~4.2014.2.~~ Transportation of removeable pockets, cards, drawers or similar technology ~~or~~ unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2)]
- ~~4.2014.3.~~ 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)]

~~4.2415~~ ~~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: \_\_\_\_\_

~~4.2216~~ 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:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**D. DEVICE REQUIREMENTS**

Yes No N/A

~~4.2317~~ 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)]~~

- 4.2518 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)]
- 4.2619 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)]
- 4.2720 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]
  - 4.271.1 The pharmacy has developed, ~~and implemented,~~ and maintained 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: \_\_\_\_\_

- 4.271.2 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~~

- 4.271.3 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)]
- 4.271.4 The pharmacist has performed all clinical services as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4119.11(d)(4)]

- ~~4.27.1.5~~ 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 contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]
- ~~4.27.1.6~~ 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)]
- ~~4.27.1.7~~ The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]
- ~~4.27.1.8~~ 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

- ~~4.282~~ The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- ~~4.293~~ 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]
- ~~4.3024~~ Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- ~~4.3125~~ The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- ~~4.3226~~ 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 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**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)]~~

- 4.3528 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 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**F. POLICIES AND PROCEDURES**

Yes No N/A

- ~~4.3629~~ 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

~~4.370~~ 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)]

~~4.381~~ 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 \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**SECTION 5: ~~APDS~~ (Check the Appropriate Box)**

- APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**
- APDS LOCATED IN A MEDICAL OFFICES ~~(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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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 APDS 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

5.148 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)]

5.159 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)]

5.1610 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)]

5.1711 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)]

5.1812 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)]

5.1913 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)]



5.2014 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

5.2115 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

5.2216 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

5.2317 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

5.2418 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

#### 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)]~~

5.2619 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)]

5.2720 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 \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

#### E. POLICIES AND PROCEDURES

Yes No N/A

5.2021 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 ~~ing~~ 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

5.2022 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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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(e), 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(e)]~~

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 \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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

6.87 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.~~

~~6.108~~ The pharmacy operating the ADDS has completed a 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 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**C. DEVICE REQUIREMENTS:**

Yes No N/A

~~6.119~~ 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~~<sup>19</sup> 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~~<sup>20</sup> 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~~<sup>21</sup> If the ADDS allows licensed personnel to have access to multiple drugs and ~~are~~<sup>is</sup> not patient specific in ~~its~~<sup>their</sup> 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 \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### 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~~<sup>21</sup> 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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**E. POLICIES AND PROCEDURES**

Yes No N/A

6.2823 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)]

6.2924 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

6.3025 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)]

6.3126 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)]~~

6.3327 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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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(c).~~

~~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 4427.6(j)]~~

~~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 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**B. PHARMACIST RESPONSIBILITY**

~~Yes No N/A~~

- ~~7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(e)]~~
- ~~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 87: 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

~~78.1~~ 78.1 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)]

~~78.2~~ 78.2 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 Code, 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

~~78.3~~ 78.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.

An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

- 78.4 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)]
- 78.5 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)]
- 78.6 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)]
- 78.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]
- 78.8 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)]
- 78.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]
- 78.10 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 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**B. POLICIES AND PROCEDURES**

Yes No N/A

- 78.121 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)]
- 78.132 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)]

- ~~78.143~~ The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]
- ~~78.154~~ 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 50242.2 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**

- ~~78.165~~ 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)]
- ~~78.176~~ 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]
- ~~78.187~~ 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)]
- ~~78.198~~ 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 \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**C. PHARMACIST RESPONSIBILITIES**

**Yes No N/A**

- ~~78.2019~~ A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

~~78.2420~~ 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**

~~78.2221~~ 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 \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**D. DEVICE REQUIREMENT**

**Yes No N/A**

~~78.2322~~ 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)]

~~78.2423~~ 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)]

~~78.2524~~ 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)]

~~78.2625~~ 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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**E. RECORD KEEPING REQUIREMENTS**

Yes No N/A

78.2726 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 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**SECTION 98:**

- 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

89.1 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)]

~~89.2~~ 89.2 ~~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~~ The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- 8.2.2 ~~is~~ are 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

~~9-38.4~~ 9-38.4 The prescriber ensures the label on the drug contains all the information required by BPC 4076 and CCR 1707.5.

~~9-48.5~~ 9-48.5 The federal warning labels prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

~~9-58.6~~ 9-58.6 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]

~~9-68.7~~ 9-68.7 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)]

~~9-78.8~~ 9-78.8 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

~~9.8.9~~ 9.9 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~~ 9.9 The operating pharmacy has obtained a license from the Board to operate the ADDS that is used for administration and dispensing which includes the address of the ADDS 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 – ADDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) ADDS 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

---

---

---

---

**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

---

---

---

---

---

---

**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 AUDES shall develop and implement, and review annually, the written policies and procedures pertaining to the AUDES. [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 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](mailto: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)]

Draft Rev. April 1, 2024



# **Attachment 4**

## Board of Pharmacy

### Enforcement Workload Statistics FY 2023/24

<b>Complaint Investigations</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	820	821	567	0	2,208
Closed	767	603	428	0	1,798
					Quarter Ending
Pending	1,932	2,203	2,335	0	2,335
Average Days for Investigation	215	209	217	0	217

<b>Cases Under Investigation (By Team)</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	745	987	1,053	0	1,053
Drug Diversion / Fraud	241	238	230	0	230
Prescription Drug Abuse	221	240	272	0	272
Compounding	40	43	33	0	33
Outsourcing	16	22	16	0	16
Probation / PRP	42	36	38	0	38
Enforcement	53	41	41	0	41
Criminal Conviction	571	594	643	0	643

<b>Application Investigations</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	64	56	31	0	151
<b>Closed</b>					
Approved	28	29	19	0	76
Denied	7	17	14	0	38
<b>Total Closed (includes withdrawn)</b>	<b>38</b>	<b>47</b>	<b>34</b>	<b>0</b>	<b>119</b>
					Quarter Ending
Pending	102	113		0	113

<b>Complaint Closure Outcomes Not Resulting in Further Action</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	229	185	149	0	563
Non-Jurisdictional	115	105	80	0	300
No Violation	51	54	46	0	151
No Further Action	33	28	16	0	77
Other - Non-Substantiated	59	27	30	0	116
Subject Educated	21	16	14	0	51

<b>Letter of Admonishments / Citations</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	47	48	24	0	119
Citations Issued	270	160	91	0	521
Proof of Abatement Requested	36	25	12	0	73
Appeals Referred to AG's Office	42	10	14	0	66
Dismissed	3	12	4	0	19
<b>Total Fines Collected</b>	<b>\$702,692</b>	<b>\$370,263</b>	<b>\$147,453</b>	<b>\$0</b>	<b>\$1,220,408</b>

<b>Administrative Cases</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	78	64	34	0	176
Pleadings Filed	75	53	39	0	167
Total Closed	46	57	48	0	151
<b>Pending</b>					Quarter Ending
Pre-Accusation	144	137	126	0	126
Post-Accusation	169	185	186	0	186
<b>Total Pending</b>	<b>313</b>	<b>322</b>	<b>312</b>	<b>0</b>	<b>312</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b>Revocation</b>					
Pharmacist	2	4	1	0	7
Intern Pharmacist	0	2	0	0	2
Pharmacy Technician	8	15	19	0	42
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
<b>Total</b>	<b>11</b>	<b>24</b>	<b>21</b>	<b>0</b>	<b>56</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b>Revocation, stayed, suspension/probation</b>					
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
<b>Total</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b>Revocation, stayed, probation</b>					
Pharmacist	8	8	5	0	21
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	3	2	0	9
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	4	1	0	7
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
<b>Total</b>	<b>14</b>	<b>15</b>	<b>8</b>	<b>0</b>	<b>37</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b><i>Surrender / Voluntary Surrender</i></b>					
Pharmacist	2	1	3	0	6
Intern Pharmacist	0	0	1	0	1
Pharmacy Technician	1	3	4	0	8
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	1	0	2
Sterile Compounding	0	1	2	0	3
Outsourcing	0	0	0	0	0
<b>Total</b>	<b>4</b>	<b>5</b>	<b>11</b>	<b>0</b>	<b>20</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b><i>Public Reproval / Reprimand</i></b>					
Pharmacist	6	4	0	0	10
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	1	1	3	0	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
<b>Total</b>	<b>8</b>	<b>5</b>	<b>0</b>	<b>0</b>	<b>13</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b><i>Licenses Granted (with or w/o conditions)</i></b>					
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
<b>Total</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>0</b>	<b>7</b>

<b>Administrative Case Outcomes</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b><i>Licenses Denied</i></b>					
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
<b>Total</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>3</b>

<b>Administrative Case Cost Recovery Efforts</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
<b>Cost Recovery Requested</b>	<b>\$361,102</b>	<b>\$211,270</b>	<b>\$124,300</b>	<b>\$0</b>	<b>\$696,672</b>
<b>Cost Recovery Collected</b>	<b>\$254,954</b>	<b>\$203,035</b>	<b>\$0</b>	<b>\$0</b>	<b>\$457,989</b>

<b>Immediate Public Protection Sanctions</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	1	2	2	0	5
Automatic Suspension Orders	1	1	2	0	4
Penal Code 23 Restrictions	2	6	0	0	8
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

<b>Probation Statistics</b>	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
<b>Licenses on Probation</b>					
Pharmacist	164	164	165	0	165
Intern Pharmacist	2	1	2	0	2
Pharmacy Technician	20	21	22	0	22
Designated Representative	1	1	1	0	1
Wholesaler / 3PL	2	2	2	0	2
Pharmacy	52	53	50	0	50
Sterile Compounding	9	10	9	0	9
Outsourcing	0	0	0	0	0
<b>Total</b>	<b>250</b>	<b>252</b>	<b>251</b>	<b>0</b>	<b>251</b>
<b>Probation Compliance Measures</b>					Total
Probation Office Conferences	18	16	8	0	42
Probation Interviews / Site Inspections	141	117	65	0	323
Probation Terminated / Completed	25	16	10	0	51
Referred to AG for Non-Compliance	0	0	0	0	0

As of 2/29/2024

## 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	12	0	57
Pharmacist-in-Charge with Fine*	13	13	6	0	32
Pharmacist no Fine	78	28	21	0	127
Pharmacist-in-Charge no Fine*	48	25	18	0	91
Pharmacy with Fine	134	87	39	0	260
Pharmacy no Fine	22	14	13	0	49
Pharmacy Technician with Fine	4	0	1	0	5
Pharmacy Technician no Fine	7	2	7	0	16
Wholesalers	0	1	1	0	2
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	5	0	27
Unlicensed Premises	2	0	1	0	3
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

<b>Pharmacists</b>	<b>%</b>	<b>Pharmacies</b>	<b>%</b>	<b>Pharmacists In Charge</b>	<b>%</b>
111295 - It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.	11%	1716 - Variation from prescription	23%	111295 - It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.	14%
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	11%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	20%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	14%
4113.7(b) - Chain community pharmacy; Quota for pharmacist or pharmacy technician duties prohibited (b) A chain community pharmacy shall not, through employees, contractors, or third parties, communicate	11%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	11%	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	14%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	11%	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	9%	1304.11(c) - Inventory Requirements; Biennial inventory date	14%
1716 - Variation from prescription	11%	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 pharmacist	9%	1715(b)(1) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: new pharmacy permit has been issued	7%
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	11%	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	7%	1715.65(a)(1)(2) - 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	7%
1304.11(c) - Inventory Requirements; Biennial inventory date	11%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	7%	1715.65(e) - The Inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory...	7%
4104(a)(c)(3)(4) - Licensed Employee, Theft or Impairment: Pharmacy Procedures	11%	1304.11(c) - Inventory Requirements; Biennial inventory date	5%	1716 - Variation from prescription	7%
1735.2(i) - The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product	6%	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	5%	1735.6(c) - Compounding Facilities and Equipment- Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy	7%
1735.3(a) - Records of Compounded Drug Products- For each compounded drug product, the pharmacy records shall include...	6%	56.10/4301(o) - Unauthorized release of protected healthcare information/Unprofessional conduct; assist in violation	5%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	7%

**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 February 2024.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Feb	Apr-Jun	23/24
<b>PRP Intakes</b>					
PRP Self-Referrals			1		1
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	5		11
<b>New Probationers</b>					
Pharmacists		6	2		8
Intern Pharmacists	1		1		2
Pharmacy Technicians	4	4	3		11
Total New Probationers	5	10	6		21
<b>PRP Participants and Recovery Agreements</b>					
Total PRP Participants	28	25	29		N/A
Recovery Agreements Reviewed	23	18	18		59
<b>Probationers and Inspections</b>					
Total Probationers	40	44	49		N/A
Inspections Completed	20	21	12		53
<b>Referrals to Treatment</b>					
Referrals to Treatment (PRP and Probationers)	1		2		3
<b>Drug Tests</b>					
Drug Test Ordered (PRP and Probationers)	404	414	306		1124
Drug Tests Conducted (PRP and Probationers)	389	407	294		1090
<b>Relapses (Break in Sobriety)</b>					
Relapsed (PRP and Probationers)	3	1	1		5
<b>Major Violation Actions</b>					
Cease Practice/Suspension (PRP and Probationer)	7	3	8		18
Termination from PRP	2		1		3
Probationers Referred for Discipline	1				1
<b>Closure</b>					
Successful Completion (PRP and Probationers)	3		1		4
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	6		32
Other (PRP)	2	2			4
<b>Patients Harmed</b>					
Number of Patients Harmed (PRP and Probationers)					Zero
<b>Drug of Choice at PRP Intake or Probation</b>					
<b>Pharmacists</b>	<b>July-Sep</b>	<b>Oct-Dec</b>	<b>Jan-Feb</b>	<b>Apr-Jun</b>	<b>Total 23/24</b>
Alcohol	2	1	3		6
Ambien					
Opiates			1		1
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					



### 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 February 2024.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Feb	Apr-Jun	23/24
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	July-Sep	Oct-Dec	Jan-Feb	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-Feb	Apr-Jun	Total 23/24
Alcohol	4	2	3		9
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 February 2024

- 1 Alcohol
- 2 Opiates
- 3 Hydrocodone
- 4 Oxycodone
- 5 Benzodiazepines
- 6 Barbiturates
- 7 Marijuana
- 8 Heroin
- 9 Cocaine
- 10 Methamphetamine
- 11 Pharmaceutical Amphetamine

