California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 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

To: Board Members

Subject: Agenda Item XI. Discussion and Consideration and Possible Action Related to Proposed Regulations to Amend title 16, California Code of Regulations Section 1715.1 and Automated Drug Delivery System Self-Assessment (Form 17M-112), Including Comments Received During the Public Comment Period

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Background:

At the January 28, 2022, Board meeting, the Board approved proposed regulation text to amend Section 1715.1 related to the Automated Drug Delivery System Self-Assessment. This proposal updates the Self-Assessment form 17M-112 as incorporated by reference in Title 16 CCR section 1715.1.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on November 11, 2022, which ended on December 27, 2022.

Attached following this memo are the following:

1. Comments received during the 45-day comment period.
2. Board staff prepared summarized comment with recommendations.
3. Amended self-assessment form to bring the legal references within the forms up to 2023 from the 2022 version, which was released for 45-day public comment.

Possible Adoption Language:

Accept the Board staff recommended comment response, approve the staff recommended modified self-assessment form, and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at Section 1715.1. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Martinez, Lori@DCA

Sent:
To:
Cc:
Subject:

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: Antotran@dmh.lacounty.gov

Hello California Board of Pharmacy,

This email is regarding the pending proposed changes to the ADDs self-assessment (Title 16, California Code of Regulations Section 1715.1).

Does the ADDs self-assessment apply to BOP licensed clinics, but are not operated by a pharmacy? Our clinics are operated by the County Mental Health Department, and we are planning to stock 5 non-controlled psychiatric medications obtained from a wholesaler in our Pyxis machines. If this applies, we recommend adding a section in Automated Drug Delivery System Self-Assessment to address requirements for establishments that are not linked to a pharmacy as, in our case, we are purchasing medications directly from a wholesaler to supply the Automated Unit Dose Systems (AUDs) located in our physicians' clinics for administration to patients in the clinic by authorized personnel. The current self-assessment only addresses ADDs that are being managed by an operational pharmacy, therefore it is unclear what the requirements are for establishments that do not fit into current categories defined by sections 5-9.

Thank you,

Antoinette Tran, PharmD
Clinical Pharmacist
LA County Department of Mental Health
Mobile: (213) 943-8877

Martinez, Lori@DCA

Sent:
To:
Subject:

To Whom It May Concern:

I am making comments in regards to the ADDS Self-Assessment within the 45-Day Comment Period of November 11, 2022 to December 27, 2022.

1. For Section 6.3 which states "The stocking of the ADDS is performed by a pharmacist…", the Board should revise this section to state that the stocking of an ADDS may be performed by a pharmacy technician or intern pharmacist under the supervision of a pharmacist as per BPC § 4427.4 (e)(1) even if the pockets, cards, or drawers are not removable. Limiting the stocking of an ADDS to a pharmacist is unnecessary and creates an undue burden on small businesses and facilities with limited resources. ADDS systems generally have scanners. When a drug is scanned, the specific drawer and cubby will open for that drug. No other drawer and cubby will open. A trained pharmacy technician or intern is more than capable of restocking an ADDS.

Thank you,
Tiffany Lao

Martinez, Lori@DCA

Sent:
To:
Cc:
Subject:
Attachments:

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: vipul.patel@cshs.org

To:
Lori Martinez
California Board of Pharmacy
2720 Gateway Oaks Drive Ste. 100
Sacramento, CA 95833

On behalf Cedars-Sinai Medical Center, Scripps Health, University of California (UC) Health/UC Medical Center Pharmacies and Sutter Health, we would like to provide comments and recommendations for the proposed ADDS Self-Assessment. Majority of ADDSs are leased and not necessarily "owned" by the entity that is utilizing the ADDS. To prevent confusion and ensure consistency with all other CA BOP Self-Assessment forms, would recommend including "pharmacy owner of ADDS or administrator" for Certification of Completion section (Page 43 of 44). Attached is a summary for your review and consideration.

Should you have any questions or concerns related to our comments/recommendations, please do not hesitate to contact me.
Thank you,

Cedars Sinai
MEDICAL CENTER
Los Angeles, CA

Vipul Patel, PharmD
Executive Director, Pharmacy & Oncology Services
Vipul.Patel@cshs.org
8700 Beverly Blvd, Suite 2800 Plaza : Los Angeles, CA 90048
Direct: 310.423.5611 : **Fax** 310.423.0412 : cedars-sinai.edu

California Board of Pharmacy Self-Assessment Draft: Automated Drug Delivery Systems (ADDS) – Comments

Institution/Contact	**Cedars-Sinai Medical Center** Department of Pharmacy Services 310-423-5611 Rita Shane, PharmD, Vice President & Chief Pharmacy Officer; rita.shane@cshs.org Vipul Patel, PharmD, Executive Director, Pharmacy & Oncology Services; Vipul.patel@cshs.org **Scripps Health** Lori Hensic, PharmD, Corporate Director of Medication Safety, Risk and Compliance; Hensic.Lori@scrippshealth.org **University of California (UC) Health and UC Medical Center Pharmacies** John Grubbs, RPh, Chief Pharmacy Officer of UC Health; John.Grubbs@ucop.edu **Sutter Health** André Pieterse, RPh, Director of Pharmacy Sutter Amador Hospital; andre.pieterse@sutterhealth.org

Certification of Completed Action Plan ACKNOWLEDGMENT BY OWNER OF ADDS:	**Recommendations:** ACKNOWLEDGMENT BY PHARMACY OWNER OF ADDS OR ADMINISTRATOR: **Comments:** Majority of ADDSs are leased and not necessarily "owned" by the entity that is utilizing the ADDS. To prevent confusion and ensure consistency with all other CA BOP Self-Assessment forms, would recommend including pharmacy owner or administrator.

From:	Loriann DeMartini
To:	Martinez, Lori@DCA; PharmacyRulemaking@DCA
Cc:	Loriann DeMartini; Sodergren, Anne@DCA; Martin Iyoya; kenfukushima84@gmail.com; Pieterse, Andre; Stice, Ryan; jdesai@stanfordhealthcare.org; jpallares@dhs.lacounty.gov; dhollander@stanfordchildrens.org; jdesai@stanfordhealthcare.org; wsamara@coh.org; Jackson, Robert
Subject:	ERRATA REQUEST - Comments on Proposed Rule Making for ADDS Self Assessment
Date:	Friday, January 13, 2023 10:26:27 AM
Attachments:	image001.jpg CSHP comments BOP ADDS rule making 12.26.2022.docx

Ms. Martinez:

Our previous communication dated December 26, 2022, regarding the above subject reference. It has come to our attention that our previous comment regarding section 1.3 of the proposed updated ADDS self-assessment contained an error. We wish to present herewith the corrected comment and suggested alternative language for your consideration.

The comments and suggested ADDS self-assessment language are:

Self Assessment Numbering Nomenclature	**Comments and suggested alternative language**
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), BPC 4056, BPC 4068]	The statute is changed from how it was originally written. Neither BPC 4056 nor 4068 makes mention of AUDS and this section effectively combines statutes. BPC 4056 and BPC 4068 was not written and intended to combine the definition of AUDS. It is our recommendation that this section be changed as follows: 1.3 The pharmacy uses an AUDS – "Automated UNIT DOSE system," an ADDS for the storage and retrieval of unit dose drugs for administration to patients. [BPC 4427.2(i).

Thank you for your consideration on this requested clarification,

Loriann

Loriann De Martini, Pharm.D., MPH, BCGP
Chief Executive Officer

California Society of Health-System Pharmacists (CSHP)

Executive Director
CSHP Research and Education Foundation

1314 H Street, Suite 200
Sacramento, CA 95814
T: 916.447.1033 ext 1002

ldemartini@cshp.org

From: Loriann DeMartini <ldemartini@cshp.org>
Sent: Monday, December 26, 2022 5:27 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>; PharmacyRulemaking@dca.ca.gov
Cc: Sodergren, Anne@DCA <Anne.Sodergren@dca.ca.gov>; Martin Iyoya <martin.iyoya@johnmuirhealth.com>; kenfukushima84@gmail.com; Pieterse, Andre <Andre.Pieterse@sutterhealth.org>; Sisodiya, Deepak <dsisodiya@stanfordhealthcare.org>; JPallares@dhs.lacounty; dhollander@stanfordchildrens.org; Stice, Ryan <SticeR@sutterhealth.org>; jdesai@stanfordhealthcare.org; wsamara@coh.org; Jackson, Robert <Robert.Jackson@cpspharm.com>; Loriann DeMartini <ldemartini@cshp.org>
Subject: Comments on Proposed Rule Making for ADDS Self Assessment

Ms. Martinez,

On behalf of the California Society of Health-System Pharmacists (CSHP) and CSHP Hospital Leaders Council we are submitting comments to the regulatory rule making proposal to amend 16 CCR section 1715.1 to update the self-assessment form that pharmacists-in-charge must complete for Automated Drug Delivery Systems (ADDS).

Sincerely,

Loriann

Loriann De Martini, Pharm.D., MPH, BCGP
Chief Executive Officer
California Society of Health-System Pharmacists (CSHP)

Executive Director
CSHP Research and Education Foundation

1314 H Street, Suite 200
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T: 916.447.1033 ext 1002

ldemartini@cshp.org

Martinez, Lori@DCA

From:
Sent:
To:
Cc:

Subject:
Attachments:

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: ldemartini@cshp.org

Ms. Martinez,

On behalf of the California Society of Health-System Pharmacists (CSHP) and CSHP Hospital Leaders Council we are submitting comments to the regulatory rule making proposal to amend 16 CCR section 1715.1 to update the self-assessment form that pharmacists-in-charge must complete for Automated Drug Delivery Systems (ADDS).

Sincerely,

Loriann

Loriann De Martini, Pharm.D., MPH, BCGP
Chief Executive Officer
California Society of Health-System Pharmacists (CSHP)

Executive Director
CSHP Research and Education Foundation

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T: 916.447.1033 ext 1002

ldemartini@cshp.org

December 26, 2022

Lori Martinez
2720 Gateway Oaks Drive Ste. 100
Sacramento, CA 95833
Email: PharmacyRulemaking@dca.ca.gov

RE: Automated Drug Delivery System regulatory rule making proposal

Ms. Martinez:

On behalf of the California Society of Health-System Pharmacists (CSHP) and CSHP Hospital Leaders Council we are submitting comments to the regulatory rule making proposal to amend 16 CCR section 1715.1 to update the self-assessment form that pharmacists-in-charge must complete for Automated Drug Delivery Systems (ADDS).

The comments and suggested ADDS self-assessment language are:

Self Assessment Numbering Nomenclature	**Comments and suggested alternative language**
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), BPC 4056, BPC 4068]	The statute is changed from how it was originally written. Neither BPC 4056 nor 4068 makes mention of AUDS and this section effectively combines statutes. BPC 4056 and BPC 4068 was not written and intended to combine the definition of AUDS. It is our recommendation that this section be changed as follows: 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), BPC 4056, BPC 4068]
2.3 Provides pharmacy services through an ADDSAUDS 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]	It is our recommendation to spell out HSC 1250 (c),(d), and (k) since HSC 1261.6 include these specific facilities as (c) skilled nursing facility, (d) intermediate care facility, (k) nursing facility by name to avoid any confusion. It is further recommended for user-friendliness and pharmacist-in-charge use to consider breaking down questions specific to subdivision (a) and (b) hospitals, (c) skilled nursing facilities, (d) intermediate care facilities, (k) nursing facilities.

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, and is used to provide doses administered to patients while in a licensed general acute care hospital and to dispense drugs 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. The quantity dispensed is limited to an amount necessary to maintain uninterrupted therapy and does not exceed a 72-hour supply. [BPC 4056, 4427.2(i)]	It is our concern that language is added to the statute combining AUDS with BPC 4056, when they are separate statutes. The statutes must be separated. In addition, it should be noted that BPC 4056 lacks the reference to a "drug room" and mentions a licensed hospital that contains 100 beds or fewer does not employ a full-time pharmacist, the wording is absent from this section and should be added to reflect the wording of the statute. Aside from the above, it is recommended that the long sentence be truncated for easier PIC understanding.
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 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)] ♦ 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 controlled substances 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 is limited to an amount necessary to maintain uninterrupted therapy, but shall	It is our concern that language is added to the statute combining AUDS with BPC 4068, when they are separate statutes. The statutes must be separated.

not exceed a 72-hour supply. Note: Licensure of AUDS operated under these provisions is required.	
2.10 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): _____	It is recommended that a selection of possible facility types be presented to PIC's versus leaving this section open to PIC interpretation by use of an open-ended question.
SECTION 6: – ADDS in a health facility pursuant to HSC 1250 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)]	It should be noted this heading refers to a health facility pursuant to HSC 1250 that complies with HSC 1261.6. This means that it only refers to subdivision facility types (c), (d) and (k). It is our recommendation to spell out HSC 1250 (c), (d) and (k) since HSC 1261.6 include specific these specific facilities as (c) skilled nursing facilities, (d) intermediate care facilities, (k) nursing facilities to avoid any confusion. It is further recommended that it be clarified that this section does not apply to HSC 1250 subsection (a) general acute care hospitals and (b) acute care psychiatric facilities. For user-friendliness, consider breaking down questions specific to hospitals vs SNF's, ICF's and nursing care facilities. Under '**A. GENERAL REQUIREMENTS'** we recommend that the deleted wording of "subdivision (c), (d) or (k)" be restored to make it consistent with the heading. It should be noted that all referenced self-assessment requirements in SECTION 6 will only apply to subdivision (c), (d) or (k) facilities.
SECTION 6, numbers 6.1 through 6.28	It should be noted that all referenced self-assessment requirements in SECTION 6 will only apply to subdivision (c), (d) or (k) facilities.
SECTION 8 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 uses for dispensing.	Please note that SECTION 8 instructs hospital pharmacies to complete Section 6 which applies to HSC 1250 subdivision (c), (d) or (k) facilities. Hospital pharmacies are generally functioning in subdivision (a) and (b) licensed facilities. Therefore, section 6 does not apply to hospital pharmacies. It is recommended that this instruction be deleted.

8~~9~~.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states they he/she intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a), (f)]	It is our concern that language is added to the statute combining AUDS with BPC 4056, when they are separate statutes. The statutes must be separated. In addition, it should be noted that BPC 4056 lacks the reference to a "drug room" and mentions a licensed hospital that contains 100 beds or fewer does not employ a full-time pharmacist, the wording is absent from this section and should be added to reflect the wording of the statute. Aside from the above, it is recommended that the long sentence be truncated for easier PIC understanding.
8~~9~~.2 The Where the prescriber in a hospital emergency room dispenses a dangerous drug, including a controlled substance, from the AUDS to an emergency room patient, the following conditions apply [BPC 4068(a)]: 8.2.1 when t The hospital pharmacy is closed and there is no pharmacist available in the hospital. ♦ 8.2.2 The drugs is are acquired by the hospital pharmacy. ♦ 8.2.3 The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens. ♦ 8.2.4 The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code. ♦ 8.2.5 The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patients. ♦ 8.2.6 The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not	It is our concern that language is added to the statute combining AUDS with BPC 4068, when they are separate statutes. The statutes must be separated. In addition, it is our concern that this section deviates significantly from the currently published HOSPITAL PHARMACY SELF-ASSESSMENT 17M-14 Rev. 1/22). https://www.pharmacy.ca.gov/forms/17m_14.pdf In essence, licensees are provided with different versions and interpretations of the statute which will confuse licensees and the public. It is recommended that statutes and regulations be displayed consistently across different published self-assessments.

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.	
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)]	It is our concern that language in BPC 4424.2(I) does not include language per section 8.3 which states "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)]" It is our recommendation that BPC 4427.2(a) be referenced and quoted.
Title 16 Board of Pharmacy Proposed Regulation **Proposal to amend §1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:** § 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge. 1715.1 (c)(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.	It is our concern that the requirement of ADDS owner review and signature is problematic for large corporations. In practice it requires a corporate officer or corporation board member review and signature. In a majority of cases these individuals are so far removed from operations that that they cannot constructively evaluate, track or review compliance. Other self-assessments require co-signature of individuals closer to daily operations such as a hospital or site administrator. It is recommended to change the regulation and ADDS Self-Assessment and change “owner” to: site owner or administrator.

Thank you for your consideration. If you have any further questions or comments, please do not hesitate to contact Loriann De Martini, PharmD, MPH, BCGP at ldemartini@cshp.org.

Respectfully,

Martin Iyoya PharmD, FCSHP
Chair, CSHP Hospital Leaders Council

Loriann DeMartini PharmD, MPH, BCGP
Chief Executive Officer, CSHP

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December 27, 2022

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Proposal to amend §1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations and to modify the Automated Drug Delivery System (17M-112) Self-Assessment Form***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to self-assessments of automated drug delivery systems and on the proposed modifications to the Automated Drug Delivery System (17M-122) self-assessment form.

Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

Kaiser Permanente continues to disagree with the Board's application of Business and Professions Code section 4427.7(a) as it relates to AUDS devices that are exempted from licensure under Business and Professions Code section 4427.2(i). The statute that dictates the conditions under which a pharmacy is required to complete an ADDS self-assessment unambiguously states that "a ***pharmacy holding an ADDS license*** shall complete a self-assessment… evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS."[1] The Board is now attempting to contravene this law by promulgating a regulation that would require hospital pharmacies that operate unlicensed AUDS devices and do not hold an ADDS license to complete the ADDS self-assessment. In attempting to establish this requirement, the Board has cited Business and Professions Code section 4427.2(i) and a discussion of the Board's policy on this matter, which is documented in the minutes of the Board's November 2019 meeting.[2] We will describe the reasons why neither Business and Professions Code section 4427.2(i) nor the Board's stated policy on ADDS self-assessments provide justification for requiring a pharmacy that does not hold an ADDS license to complete the ADDS self-assessment.

Business and Professions Code section 4427.2(i) exempts AUDS devices that are operated by a licensed hospital pharmacy from the requirement to obtain an ADDS license if several conditions are met. Additionally, the statute requires that "[t]he AUDS shall comply with all other requirements for an ADDS in this article."[3] However, the statutory requirement to complete an ADDS self-assessment is contingent upon the pharmacy holding an ADDS license. Specifically, the statute states, "a ***pharmacy holding an ADDS license*** shall complete a self-assessment… evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS."[4] Therefore, if a

[1] Cal. Bus. & Prof. Code § 4427.7(a).
[2] California Board of Pharmacy, *November 2019 Full Board Meeting Minutes*, https://www.pharmacy.ca.gov/meetings/minutes/2019/19_nov_bd_min.pdf (last visited Dec. 12, 2022).
[3] Cal. Bus. & Prof. Code § 4427.2(i).
[4] Cal. Bus. & Prof. Code § 4427.7(a).

pharmacy that operates an AUDS that is exempted from licensure is to comply with "all other requirements for an ADDS in this article," then to comply with Business and Professions Code section 4427.7(a), the pharmacy would only complete the ADDS self-assessment if it held an ADDS license—for example, a license for an APDS device that is also operated by that pharmacy. Conversely, if the pharmacy does not hold an ADDS license, then it is in compliance with Business and Professions Code section 4427.7(a) when it does not complete the ADDS self-assessment, even if it operates an unlicensed ADDS.

The minutes of the Board's November 2019 meeting memorialize the Board's discussion of its policy on the completion of the ADDS self-assessment for exempt non-licensed AUDS devices. For the sake of completeness, that entire section of the minutes is copied below:

> Ms. Veale provided to clarify BPC 4427.7 requires a "pharmacy holding an ADDS license" to complete the self-assessment. However, licensed acute care hospital facility and acute psychiatric hospital facilities are exempt from licensure if the ADDS is owned/leased by the licensed hospital pharmacy and the drugs are owned by the licensed hospital pharmacy. BPC 4427.2(i) also requires the licensed hospital pharmacy to comply with all other requirements for an ADDS in the article. Although the licensed hospital pharmacy's ADDS are not licensed, ***they should also complete the self-assessment*** if they are to comply with all other requirements for an ADDS.[5]

A careful reading of the Board's November 2019 policy statement clearly indicates that the Board encourages pharmacies that operate exempt non-licensed AUDS devices to complete the ADDS self-assessment but does not require them to do so. The Board's selection of the word "should" rather than "shall" or "must" clearly indicates that the Board's policy was not to establish an explicit requirement for pharmacies that operate exempt non-licensed AUDS devices to complete the ADDS self-assessment but to encourage those pharmacies to consider doing so.

Based on the underlying statute from which the Board derives the authority to require pharmacies to complete the ADDS self-assessment and the Board's previously stated policy on the completion of the ADDS self-assessment by pharmacies that operate exempt non-licensed AUDS devices, it is clear that a pharmacy that does not hold an ADDS license cannot be required to complete the ADDS self-assessment. If the Board believes that all hospital pharmacies that operate unlicensed AUDS devices should be required to complete the ADDS self-assessment, then the Board should sponsor a bill to amend Business and Professions Code section 4427.7(a) to establish such a requirement. Because the proposed changes to the regulation are inconsistent with the underlying statute, we recommend that the Board make the following changes to the regulation:

> Kaiser Permanente's requested changes are indicated in red font. Suggested deletions are indicated with a ~~strikethrough~~ and suggested additions are indicated with an underline.
>
> 1751.1(f) The pharmacist-in-charge of a hospital that uses an unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) shall complete a self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems if the pharmacy holds an ADDS license.
>
> (1) If a self-assessment is required, 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~~A) 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; and

[5] California Board of Pharmacy, *November 2019 Full Board Meeting Minutes*, https://www.pharmacy.ca.gov/meetings/minutes/2019/19_nov_bd_min.pdf (last visited Dec. 12, 2022).

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(~~2~~B) The same policies and procedures required by Section 4427.2 of BPC are used.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining to self-assessments of automated drug delivery systems and on the proposed modifications to the Automated Drug Delivery System (17M-122) self-assessment form. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully submitted,

John P. Gray, PharmD, MSL
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Proposed Regulation to Amend Title 16 CCR Section 1715.1, ADDS Self-Assessment

Summarized 45-day Comments Regarding Inventory Reconciliation with Board Staff Recommendations:

Written Comments from Antoinette Tran, Pharm.D.

Comment 1: The commenter requested clarification on requirement for the self-assessment form to be completed by clinics licensed with the Board of Pharmacy when the clinic is operated by the County Mental Health Department and not a pharmacy.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The regulations proposed apply only to a pharmacy operating an ADDS, not a clinic operating an ADDS.

Written Comments from Tiffany Lao.

Comment 2: The commenter recommended that section 6.3 be amended to include the ability for a pharmacy technician or intern to stock **or** restock an ADDS under the supervision of a pharmacist, which would be consistent with BPC 4427.4(e)(1).

Response to Comment 2: Board staff have reviewed this comment. Board staff recommend a change to the form to clarify that a pharmacy intern or pharmacy technician may restock in addition to the restocking options established in HSC 1261.6.

Written Comments from Vipul Patel, Pharm.D.

Comment 3: The commenter recommended that the certification signed on the last page be amended to Acknowledgment by Pharmacy Owner of ADDS or Administrator (added language underlined). The commenter indicates a majority of ADDSs are leased and not necessarily "owned" by the entity that is utilizing the ADDS, so the added language would prevent confusion.

Response to Comment 3: Board staff have reviewed this comment and recommend amending the language on the form to read "Acknowledgement of Owner of the Pharmacy or Hospital Administrator Operating the ADDS". Further, staff recommend updating certification language as follows: "I, _____ [insert

name and title], hereby certify under penalty of perjury under 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 Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete. 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.

Written Comments from Loriann DeMartini, California Society of Health-System Pharmacists, Pharm.D.

Comment 4: The commenter recommended that section 1.3 be amended to remove "by a physician in a drug room or hospital emergency room when the pharmacy is closed" as BPC 4056 and 4068 do not mention AUDS devices and were not intended to be included with AUDS devices.

Response to Comment 4: Board staff have reviewed this comment and do not recommend the change offered by the commenter. Staff, however, do suggest inclusion of an additional reference of BPC 4427.65 to section 1.3 on the self-assessment form to provide clarity to the regulated public.

Comment 5: The commenter recommended that section 2.3 be amended to specify skilled nursing facility, intermediate care facility, and nursing facility as complying with HSC 1261.6 to avoid confusion. Further, commenter recommends breaking down the specific questions by facility type.

Response to Comment 5: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the language on the form mirrors the statute. Additionally, by mirroring the statute, it ensures consistency of information and provides the specific legal sections that allows the pharmacist-in-charge to reference if clarification is needed.

Comment 6: The commenter recommended that section 2.8 be amended to separate the requirements of BPC 4427.2(i) and 4056 as they are two separate statutes. Additionally, commenter recommended removal of the term "drug room" as it is not identified in the statute. Finally, the commenter recommended that the language be shorted for ease of understanding by the PIC.

Response to Comment 6: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that statutes are not taken separately, but collectively establish the requirements. Additionally, Board staff note to the term "drug room" is utilized by the Board referenced within the form as a licensed hospital that contains 100 beds or fewer.

Comment 7: The commenter recommended that section 2.9 be amended to separate the requirements of BPC 4427.2(i) and 4068 as they are two separate statutes.

Response to Comment 7: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that statutes are not taken separately, but collectively establish the requirements.

Comment 8: The commenter recommended that section 2.10 be amended to include a list of facility types for the PIC to select from instead of utilizing an open-ended question that is subject to the PICs interpretation.

Response to Comment 8: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the language on the form mirrors the statute, which ensures consistency of information. The form includes related references for the PIC to consult should they need additional clarification on which types of facilities are eligible.

Comment 9: The commenter recommended that all requirements listed within Section 6 and the general requirements be amended to specify skilled nursing facility, intermediate care facility, and nursing facility as complying with 1261.6 to avoid confusion and to clarify that it doesn't apply to general acute care hospitals and acute care psychiatric facilities.

Response to Comment 9: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the language on the form mirrors the statute. Additionally, by mirroring the statute, it ensures consistency of information and provides the specific legal sections that the pharmacist-in-charge can refer to if clarification is needed. Board staff also notes that provisions apply to all health facilities licensed pursuant to HSC 1250, not those only referenced in HSC 1261.6.

Comment 10: The commenter recommended that the "Note" under Section 8 be removed because Section 6 does not apply to hospitals or drug rooms.

Response to Comment 10: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that section 6 provides the requirements for ADDS used for administration, as indicated on the form. Where a hospital ER is using an ADDS for dispensing as allowed under 4068 and a drug room as allowed under 4056, the provisions included in Section 8 are applicable.

Comment 11: The commenter recommended that section 2.8 be amended to separate the requirements of BPC 4427.2(i) and 4056 as they are two separate statutes. Additionally, commenter recommended removal of the term "drug room" as it is not identified in the statute. Finally, the commenter recommended that the language be shorted for ease of understanding by the PIC.

Response to Comment 11: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that statutes are not taken separately, but collectively establish the requirements. Additionally, Board staff note to the term "drug room" is utilized by the Board referenced within the form as a licensed hospital that contains 100 beds or fewer.

Comment 12: The commenter recommended that section 8.2 be amended to separate the requirements of BPC 4427.2(i) and 4068 as they are two separate statutes. Additionally, the commenter states the language within the section deviates significantly from the form 17M-14 – Hospital Pharmacy Self-Assessment.

Response to Comment 12: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that statutes are not taken separately, but collectively establish the requirements.

Comment 13: The commenter recommended that section 1751.1(c)(6) be amended to change the term "owner" to "site owner or administrator" as the use of the term "owner" requires a corporate officer or Board member to sign, which is problematic for large corporations.

Response to Comment 13: Board staff have reviewed this comment and recommend amending the language on the form to read "Acknowledgement of Owner of the Pharmacy or Hospital Administrator Operating the ADDS".

Written Comments from John Gray, Kaiser Permanente, Pharm.D.

Comment 14: The commenter disagrees with the requirement for hospitals to complete the ADDS self-assessment form for unlicensed AUDS devices. The commenter states that the requirement for the completion of the ADDS self-assessment is specific to a "pharmacy holding an ADDS license" per BPC 4427.7(a) and BPC 4427.2(i) exempts these devices from licensure. The commenter does not agree that section BPC 44727.2(i) requires compliance with the self-assessment requirement. Commenter recommends that 1751.1(f) be amended to read as follows (added language underlined):

1751.1(f) The pharmacist-in-charge of a hospital that uses an unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) shall complete a self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems if the pharmacy holds an ADDS license.

(1) If a self-assessment is required, 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:

Response to Comment 14: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. While BPC 4427.2(i) exempts an AUDS devices in a licensed hospital under specific circumstances, the statute also states that the AUDS shall comply with all other requirements for the ADDS within Article 25, which includes the requirement for the completion of the self-assessment. Additionally, board staff note that the Board has had several policy discussions on this topic, most recently at the January 2022 Enforcement Committee and Board meetings (materials and minutes available on the Board's website: https://www.pharmacy.ca.gov/about/meetings.shtml.

Title 16. Board of Pharmacy
Proposed Regulation Text

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

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

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

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  (1) A new automated drug delivery system license has been issued.
  (2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
  (3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/~~18~~2~~2~~3) 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; and
(2) The same policies and procedures required by Section 4427.2 of BPC are used.

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, 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.

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

2023 changes are shown by *~~italicized double strikethrough~~* for deleted language and *italicized wavy 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 ADDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the ADDS. 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 if the mechanical devices used are the same and the same policies are procedures are used. (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 Date:** _____
DEA Registration #: _____ **DEA Expiration Date:** _____
DEA Inventory Date: _____ **Last ~~C2~~ CS Inventory Reconciliation Date (CCR 1715.65(c)):** _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____
PIC: _____ **RPH#**_____
ADDS License #: _____ **ADDS Expiration Date:** _____
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), ~~BPC~~ 4056, ~~BPC~~4068]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

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

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

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

~~Yes No N/A~~

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

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

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

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029 of the Business and Professions Code, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25 of the Business and Professions Code. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC 4427.2(i)]

☐☐☐ 2.8 **AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room)**, as defined in section 4056 of the Business and Professions Code, and is used to provide doses administered to patients while in a licensed general acute care hospital and to dispense drugs 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. The quantity dispensed is limited to an amount necessary to maintain uninterrupted therapy 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 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)]

- ☐ 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 controlled substances 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 is limited to an amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply.

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

☐☐☐ 2.10 **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): _____

☐☐☐ 2.11 **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)]

Yes No N/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)]

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

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

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

☐☐☐ 3.10 The ADDS license~~(s)~~ 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)]

Yes No N/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), 4119.11(a)(3)]

☐☐☐ 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)(D), 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]

Yes No N/A

☐☐☐ 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), BPC 4119.11(j)]

☐☐☐ 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 (e), 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.~~

☐☐☐ *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 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 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 clinic (BPC 4180 or 4190) 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)*

☐☐☐ 3.3~~4~~*1* 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_____

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

Please Note: The Pharmacist-in-Charge of the pharmacy and the pharmacy owner of the ADDS shall sign the Certification Acknowledgment on page ~~33~~ 48 after completing the assessment.

☐ SECTION 4: ~~–~~APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.

☐ SECTION 5: ~~ADDS~~

- APDS adjacent to the secured pharmacy area (or)
- APDS located in a Medical Office~~s~~ (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, HSC 1204.1, BPC 4180, or BPC 4190.

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

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

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

☐ SECTION ~~9~~8:

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

☐ SECTION 9:

- AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)
- AUDS through a jail, youth detention facility, or other 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)]

Yes No N/A

☐☐☐ 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_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

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

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

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

Date of Inspection: _____

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

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

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

Yes No N/A

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10), 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**~~

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11), CCR 1713(f)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed a~~n annual~~ biennial Self-Assessment pursuant to CCR 1715.1 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____
Reason: ☐ Biennial; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

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

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

☐☐☐ 4.1~~8~~6 The underlying operating pharmacy is solely responsible for: [BPC 4119.11(a)(5), (6)]

- ☐ 4.16.1 The security of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.2 The operation of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.3 The maintenance of the APDS. [BPC 4119.11(a)(5)]
- ☐ 4.16.4 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: _____
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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.1~~9~~7 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.~~20~~18 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

- ☐ 4.~~20~~18.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]
- ☐ 4.~~20~~18.2 Transportation of removeable pockets, cards, drawers or similar technology o~~O~~r unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]
- ☐ 4.~~20~~18.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.~~21~~19 ~~The~~ A pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.~~22~~20 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE:

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D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.2~~3~~1 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)]~~

☐☐☐ 4.2~~5~~2 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)]

☐☐☐ 4.2~~6~~3 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)]

☐☐☐ 4.2~~7~~4The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐ 4.2~~7~~4.1 The pharmacy has developed, ~~and~~ implemented, and maintained~~s~~ written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1)~~(d)(1)(F)~~, CCR 1713(e)]

☐ 4.24.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.

☐ 4.24.1.2 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.

☐ 4.24.1.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.

☐ 4.24.1.4 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.

☐ 4.24.1.5 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.

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

Date of Last Policy Review: _____

☐ 4.2~~7~~4.2 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), CCR 1713(d)(1)]

~~Yes No N/A~~

☐ 4.2~~7~~4.3 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)(3)]

☐ 4.2~~7~~4.4 The pharmacist has performed all clinical services as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐ 4.2~~7~~4.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential~~s~~ contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]

☐ 4.2~~7~~4.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board-licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐ 4.2~~7~~4.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐ 4.2~~7~~4.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

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

☐☐☐ 4.2~~8~~5 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

Yes No N/A

☐☐☐ 4.2~~9~~6 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.~~30~~27 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.~~31~~28 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.~~32~~29Medication guides are provided on required medications. [~~(~~21 CFR 208.1]~~)~~

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

- ☐ 4.30.1 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.
- ☐ 4.30.2 The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.
- ☐ 4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
- ☐ 4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

☐☐☐ 4.3~~5~~1 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.3~~6~~2 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)]:

- ☐ 4.32.1 Maintaining the security of the APDS and dangerous drugs and devices within the APDS.
- ☐ 4.32.2 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.
- ☐ 4.32.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 4.32.4 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.
- ☐ 4.32.5 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.
- ☐ 4.32.6 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: _____

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

☐☐☐ 4.3~~8~~4 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ~~ADDS~~

- ☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**
- ☐ **APDS LOCATED IN MEDICAL OFFICES ~~(OR)~~**
- ☐ **APDS A LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE~~(OR).~~**
- ☐ **APDS THROUGH 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.~~

☐☐☐ 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 deliver of prescription medication to the patient.

☐ 5.2.2 The APDS has a means of identifying each patient and only release that patient's prescription medication to the patient or patient's agent.

☐ 5.2.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

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

Yes No N/A

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

1._____ 2. _____

3._____ 4. _____

5._____ 6. _____

7._____ 8. _____

9._____ 10._____

11. _____ 12._____

13._____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

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

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

Yes No N/A

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

~~Yes No N/A~~

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

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

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

~~Date of Last Self-Assessment: _____~~

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

~~Yes No N/A~~

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

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

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

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

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

Yes No N/A

☐☐☐ 5.~~14~~8 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

☐☐☐ 5.~~15~~9 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.~~16~~10 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.~~17~~11 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 5.~~18~~12 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.~~19~~13 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.~~20~~14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.~~21~~15 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]

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

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

☐☐☐ 5.~~24~~18 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

☐☐☐ 5.~~26~~19 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.~~27~~20 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.~~28~~21 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are maintained and reviewed annually: [BPC 4427.6(a)~~, 4427.6(a)(6)~~, CCR 1713(e)]

- ☐ 5.21.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 5.21.2 Determining~~e~~ and applying inclusion criteria regarding which drugs and~~,~~ devices are appropriate for placement in the APDS and for which patients.
- ☐ 5.21.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 5.21.4 Describing assignment of responsibilities and training of pharmacy personnel

and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.

☐ 5.21.5 Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

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

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.~~29~~22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~4105.5(c)~~, CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 ~~– LONG TERM CARE FACILITIES~~ THAT COMPLIES WITH HSC 1261.6

A. GENERAL REQUIREMENTS

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

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]

Yes No N/A

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

☐☐☐ 6.~~2~~1The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

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

☐☐☐ 6.~~4~~2 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.~~5~~3 The stocking of the ADDS is performed by a pharmacist, or, if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers ~~are used~~, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [*BPC 4427.4(e)(1),* 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. [*BPC 4427.4(e)(1),* 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)]

Yes No N/A

☐☐☐ 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 in ink, signed, and dated by the prescriber.

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

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

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

Yes No N/A

☐☐☐ 6.~~8~~7 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6(h)]

Date of Last Review: _____

☐☐☐ 6.~~9~~8 The p~~P~~harmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

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

☐☐☐ 6.~~10~~9 The pharmacy operating the ADDS has completed a~~n~~ biennial Self-Assessment pursuant to BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. ~~(~~[BPC 4427.7(a)]~~)~~

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.~~11~~10 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(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~~11 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~~12 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~~13 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~~14 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~~15 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~~16 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~~17 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~~18 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~~19 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~~20 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~~21 If the ADDS allows licensed personnel to have access to multiple drugs and ~~are~~ is not patient specific in its~~their~~ design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. ~~(~~[HSC 1261.6(f)(7)]~~)~~.

Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

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

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

Yes No N/A

☐☐☐ 6.~~27~~22 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)]

☐☐☐ 6.23 Records of inspections completed by the pharmacist are kept for at least three years. [HSC 1261.6(b), 22 CCR 70263(f)(3)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.~~28~~24 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.~~29~~25 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.~~30~~26 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.~~31~~27 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

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

☐☐☐ 6.~~33~~28 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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

A. GENERAL REQUIREMENTS

Yes No N/A

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

License number: _____ Expiration Date: _____

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

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

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

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

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

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

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

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

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

Date of last inventory_____

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

Yes No N/A

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

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

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

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

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

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

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(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 4427.6j)]

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

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

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

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

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

Date of Last Review: _____

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

Yes No N/A

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

C. POLICIES AND PROCEDURES

Yes No N/A

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

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

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

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

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

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

SECTION ~~8~~7: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 7~~8~~.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Co~~n~~de, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. ~~(~~[BPC 4187(a)].

~~Yes No N/A~~

☐☐☐ 7~~8~~.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a), 4187.2]

- The direction~~s~~ of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2]

☐☐☐ 7~~8~~.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.1(b), 4187.2]

Yes No N/A

☐☐☐ 7~~8~~.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record~~-~~keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 7~~8~~.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

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

☐☐☐ 7~~8~~.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 7~~8~~.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 7~~8~~.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7~~8~~.1~~2~~1 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 7~~8~~.1~~3~~2 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge

servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

Yes No N/A

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

☐☐☐ 7~~8~~.1~~5~~4 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 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)]

☐☐☐ 7~~8~~.1~~6~~5 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 7~~8~~.1~~7~~6 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures~~ California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2, 4187.3]

☐☐☐ 7~~8~~.1~~8~~7 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services Health Care Department Operations Manual ~~Policies and Procedures~~ to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 7~~8~~.1~~9~~8 All policies and procedures are maintained either in an electronic form or paper form at the location where the ~~automated drug system~~ ADDS is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

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

☐☐☐ 7~~8~~.~~21~~20 Drugs removed from the ~~automated drug system.~~ADDS ~~is~~ are removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. ~~If the correctional pharmacy is closed,~~ Where administration of the drug is necessary before a pharmacist has reviewed the prescription and if, in the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the ~~automated drug delivery system.~~ADDS and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the ~~statewide Inmate Medical Services Policies and Procedures.~~California Correctional Health Care Services Health Care Department Operations Manual. Any removal of the medication from an ~~automated drug delivery~~ ADDS ~~system~~ is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 7~~8~~.~~22~~21 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the ~~automated drug delivery system.~~ADDS, an inspection of the ~~automated drug delivery system.~~ADDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 7~~8~~.~~23~~22 Drugs removed from the ADDS ~~is~~ are provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 7~~8~~.~~24~~23 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 7~~8~~.~~25~~24 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 7~~8~~.~~26~~25 Drugs from the ADDS in the correctional clinic are removed by a person authorized to stock the ADDS, or by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 7~~8~~.~~27~~26 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and ~~is~~are preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION ~~9~~8:

☐ **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 (DRUG ROOM) OR**

☐ **HOSPITAL PHARMACY: AUDS USED FOR DISPENSING PURSUANT TO BPC 4068**

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 uses for dispensing.

A. GENERAL REQUIREMENTS

Yes No N/A

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

☐☐☐ 8~~9~~.2 ~~The~~ Where the prescriber in a hospital emergency room dispenses a dangerous drug, including a controlled substance, from the AUDS to an emergency room patient, the following conditions apply [BPC 4068(a)]:

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

Yes No N/A

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

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

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

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

☐☐☐ ~~9.5~~8.6 The prescription drug is dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ ~~9.6~~8.7 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as

reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4068(a)(4), HSC 11165(d)]

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

Yes No N/A

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

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

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

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

☐☐☐ 8.11 Black box warning 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_____

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SECTION 9 – AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH DETENTION FACILITY, OR OTHER CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED WITH THE FACILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR.

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_____

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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.

☐☐☐ 9.3 The pharmacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures the following: [CCR 1715.65(h)]

☐ 9.3.1 All controlled substances added to an ADDS are accounted for.

☐ 9.3.2 Access to the ADDS is limited to authorized facility personnel.

☐ 9.3.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.

☐ 9.3.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

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

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)]:

Yes No N/A

☐☐☐ 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)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, 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)]

☐☐☐ 9.10 The pharmacy providing services to the facility 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 AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the ADDS. [BPC 4427.65(b)]

☐☐☐ 9.15 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 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 HOSPITAL ADMINISTRATOR OPERATING THE ~~OF~~* ADDS:

I, ~~*(please print)*~~ _____ *[insert 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 Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is 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 _____

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 *OF THE PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING THE ~~OF~~* ADDS:

I, ~~*(please print)*~~ _____ *[insert 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 Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is 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 _____