



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 VII. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

(b) Proposed Regulations to Amend Title 16 CCR Sections 1711 and 1713 and to Add Title 16 CCR Section 1715.1, Related to Automated Drug Delivery Systems

Background:

At the January 2019 Board meeting, the Board approved proposed text to amend Section 1711 and 1713 and add Section 1715.1 related to Automated Drug Delivery Systems. This proposal will require submission of quality assurance records to the Board, update the Board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on July 3, 2020, which ended on August 17, 2020. Several comments were received during the comment period. Attached following this memo are the following:

1. Comments received during the 45-day comment period
2. Board staff prepared summarized comments with recommendations
3. Board staff recommended modified text
4. The proposed text released for 45-day public comment.

In addition to the comment received, Board staff recommend that section 1715.1 be amended to include the option for digital signatures. Under California law, digital signatures have the same force and effect as the use of a manual signature if and only if it embodies all of the following attributes:

- (1) It is unique to the person using it.
- (2) It is capable of verification.
- (3) It is under the sole control of the person using it.
- (4) It is linked to data in such a manner that if the data are changed, the digital signature is invalidated.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed for 45-day comment on July 3, 2020.
2. Amend the regulation to address concerns expressed by stakeholders and as recommended

by Board staff and notice the modified text for a 15-day comment period.

Possible Amendment Language: Accept the Board staff recommended comment responses and approve the modified language, as recommended by Board staff, and initiate a 15-day public comment period. Additionally, should no negative comments be received, 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.

1. Comments received during
the 45-day comment period



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

August 11, 2020

California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Via Email: Lori.Martinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulation Title 16, Section 1711, Section 1713, Section 1715.1, Article 2 Division 17, of Title 16 of the California Code of Regulations

The California Hospital Association and its 400 plus members appreciate the focused efforts the Board of Pharmacy has placed on the automated drug delivery system (ADDS) regulations and the specification of the two categories of ADDS, automated patient dispensing system (APDS), and automated unit dose system (AUDS). We particularly appreciate the exception granted in California Code Section 4427. 2, that states:

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section 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 this article. 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.

With this in mind, we believe the proposed addition to 16 CCR 1711(f), "Further any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review " is a statement specifically directed for licensed ADDS and not unlicensed AUDSs used in a general acute care hospital facility or a licensed acute psychiatric hospital facility. As the proposed regulation is presently worded, we believe that a GACH would be required to submit quality assurance records for all medication errors related to the use of ADDS because these are technically categorized under the Board of Pharmacy's definition of ADDS.

Our members describe a robust process for quality assurance measures for AUDSs. Medication errors are evaluated and documented as part of our existing quality assurance program under California code 4125. Events involving controlled substances diversion are reported immediately. In addition, hospital and health system policies, procedures and security measures are in place to prevent diversion and theft as existing standards of practice. The current hospital pharmacy self-assessment includes a section on ADDs and review of ADDS to demonstrate that the elements are consistent with current and customary practices.

We therefore offer two recommendations to 1711(f)- Quality Assurance Program. First, to specify that the ADDS is a "licensed" ADDS, to expressly exclude the AUDS units operated by GACH acute and psychiatric hospitals. And second, for the licensed ADDSs to "notify" the board of quality assurance records related to the use of APDS or other ADDS, versus submitting a copy of the report within 30 days. We believe that if any quality assurance records related to the use of an APDS were generated they could be reported to the board during license renewal. An additional field could be added to the ADDS license renewal form to achieve this.

And finally, we offer our observation that Section 1713(d)(2) is not congruent with California Code 4427.6(c), which states, "(c) The 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.**" Adding this would add clarity and consistency with the code section.

Section	BoP Proposed Language	Recommendations
1711(f) – Quality Assurance Program	Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.	Further, any record related to the use of a <i>licensed</i> automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.
	Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.	Further, <i>any licensee with a record</i> related to the use of an automated drug delivery system, must also <i>notify</i> the board during license renewal if any quality assurance records related to the use of APDS were generated.
1713(d)(2) -	The APDS has a means to identify each patient and only release that patient's prescription medications.	The APDS has a means to identify each patient and only release the patient's prescription medication <i>to the patient or the patient's agent</i>

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,



BJ Bartleson, RN, MS, NEA-BC
VP Nursing and Clinical Services

8/17/2020

Lori Martinez
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
(916) 518-3078
Lori.Martinez@dca.ca.gov

Dear Ms. Martinez,

I am writing to you in my capacity as Senior Director of Regulatory Affairs for CVS Health, in regards to the California Board of Pharmacy's Notice of Proposed Action for Title 16, California Code of Regulations, Section 1711, 1713, and 1715.1, entitled Automatic Drug Delivery Systems.

CVS Health believes that the pending changes to 1711(f) are unclear and nebulous, create an undue burden, and will result in excessive paperwork received by the Board. We request that the Board provide further clarity as to the term "any record". Numerous reports exist that are considered a "record related to the use of an automated drug delivery system" that have no bearing on the quality assurance review. Typically, activities that are not related to the specific acts of loading or withdrawal of medications from the ADDS are not relevant. For example, we believe that reports such as transaction reports, authorization documentation, operating systems' workflow, delivery manifests, proof of delivery, and restock reports may be pertinent, but that reports such as user access lists, inventory levels, usage reports, and expired audits likely do not pertain. Therefore, CVS Health offers the following suggested changes:

Further, any record related to a medication error associated with the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.

Thank you for considering these changes, and I look forward to the pending regulation hearing.

Sincerely,



Mark Johnston, R.Ph
CVS Health, Senior Director, Pharmacy Regulatory Affairs



August 7, 2020

California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Submitted via email to: Lori.Martinez@dca.ca.gov

SUBJECT: Proposed Regulations Related to Automated Drug Delivery Systems

To Whom It May Concern:

Providence St. Joseph Health appreciates the opportunity to comment on the Board of Pharmacy’s proposed regulations related to automated drug delivery systems (ADDS).

We believe the Board is proposing revisions to Section 1711(f) to focus on licensed ADDS, specifically automated patient drug dispensing systems (APDS). Automated unit dose systems (AUDS) operated by hospital pharmacies do not furnish/dispense medications directly to the patient. The drugs are dispensed to authorized personnel (e.g. licensed nurses/physicians) who administer them to the patient per prescriber order. Hospitals have taken steps to ensure safe dispensing and administration, and we are required to improve safety in these procedures per medication error review as part of the medication error reduction plan (MERP) regulations under Health & Safety Code, Section 1339.63.

PSIH Recommendation

Section	Proposed Language	Recommendation
1711(f) – Quality Assurance Program	The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. <u>Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.</u>	<i>The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. <u>Further, any record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.</u></i>

Thank you for considering our comments on the proposed regulations.

Sincerely,

Michael Tou
Executive Director, Government & Public Affairs



RECEIVED

AUG 06 2020

California State
Board of Pharmacy

July 29th, 2020

Lori Martinez

Administration & Regulations Manager

California State Board of Pharmacy

2720 Gateway Oaks Drive Ste. 100

Sacramento, CA 95833

Lori.Martinez@dca.ca.gov

Re: Proposed regulations for Automated Drug Delivery Systems

Dear Lori,

Thank you for the opportunity to provide feedback on the Board's proposed regulations related to Automated Drug Delivery Systems. We have attached our recommendations/comments for your consideration.

Should you have any questions, please feel free to contact me directly.

Sincerely,

A handwritten signature in blue ink that reads 'Rita Shane'.

Rita Shane, PharmD, FASHP, FCSHP

Chief Pharmacy Officer, Professor of Medicine

Department of Pharmacy Services

Assistant Dean, Clinical Pharmacy, UCSF School of Pharmacy

Office: 310-423-5611

Email: shane@cshs.org

**California State Board of Pharmacy Automated Drug Delivery Systems
Proposed Regulations – Comments**

Institution/Contact	Cedars-Sinai Medical Center Department of Pharmacy Services 310-423-5611 Rita Shane, PharmD, Chief Pharmacy Officer; shane@cshs.org	
Subdivision	Proposed Language	Recommendations/ Comments
1711.f	The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. <u>Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.</u>	<p><u>Recommendation:</u> Revise proposed regulations to: "The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review. <u>This section shall not apply to automated unit dose system located within a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety code.</u>"</p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> • Our understanding is that the intent of the proposed regulations is to ensure quality and safety with Automated Drug Delivery Systems (ADDs). For Automated Unit Dose System (AUDS) that are operated under the General Acute Care license, medication errors are evaluated and documented as part of the existing State Board Requirement for pharmacy quality assurance program with records readily available during inspections (CCR 1711). • Hospital policies and procedures and security measures are in place to prevent diversion and theft as an existing standard of practice to meet existing regulatory requirements and controlled substance losses are reported to the Board within 30 days (CCR 1715.6). Events involving controlled substances diversion would be reported immediately as is the current practice.
1715.1.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	<p><u>Recommendation</u> Revise proposed regulations to add a new section 1715.1.f : "(f) <u>This section shall not apply to automated unit dose system located within a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety code.</u>"</p> <p><u>Comments:</u></p>

**California State Board of Pharmacy Automated Drug Delivery Systems
Proposed Regulations – Comments**

	<p>Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.</p>	<p>The current hospital pharmacy self-assessment includes a section on ADDs and a review of the ADDS self-assessment demonstrates that the elements are consistent with current health-system practices.</p>
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August 17, 2020

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 Sections 1711, 1713, and 1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations

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 Automated Drug Delivery Systems (ADDS).

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.

Quality Assurance Record Submission

It is possible that the proposed addition to 16 CCR 1711(f) on quality assurance programs that "any [quality assurance] record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion..." is more broad than the Board intended. Specifically, we seek clarification if a general acute care hospital would be required to submit quality assurance records for all medication errors related to the use of automated dispensing machines because those devices are Automated Unit Dose Systems (AUDS) under the Board's definition of ADDS. Because Automated Patient Dispensing Systems (APDS) are a relatively new technology, it could be of benefit for the Board to have increased visibility to medication errors involving APDS devices. Conversely, the AUDS devices used to distribute medications in hospital and health system settings are a mature technology that have been in use since the late 1980s. Because BPC 4427.2(i) exempts AUDS devices that are "used solely to provide doses administered to patients while in a licensed general acute care hospital facility," from the ADDS licensure requirement, we seek clarification on whether it was the Board's intent to require quality assurance records related to the use of AUDS devices to be submitted to the Board. We are also concerned that, compared to the current requirement to maintain all other quality assurance records in the pharmacy, the requirement to submit all ADDS-related quality assurance records to the Board will be burdensome to the regulated public while providing questionable benefit to California consumers. We suggest that a requirement to notify the Board during license renewal if any quality assurance records related to the use of an APDS were generated would provide an appropriate amount of information to the Board about errors involving ADDS devices. Therefore, in order for the Board to have increased visibility to the frequency of errors involving APDS devices while eliminating the possible requirement to

supply quality assurance records involving AUDS devices, we recommend the following change to 16 CCR § 1711(f):

The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. ~~Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review at the time of each Automated Patient Dispensing System license renewal, the licensee shall disclose to the board whether any quality assurance records have been generated for the APDS since the license was last renewed or issued.~~

Patient’s Agent Picking Up from APDS

The Board has proposed several changes to 16 CCR 1713 such that it will conform with Article 25 of California Business and Professions Code on ADDS devices. Business and Professions Code Section 4427.6(c) states that an “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”. The Board has proposed that the amended 16 CCR 1713(d)(2) should read “The APDS has a means to identify each patient and only release that patient’s prescription medications”. We suggest that the Board should consider whether it would be of benefit to amend 16 CCR 1713(d)(2) such that it is identical to BPC 4427.6(c) in order to eliminate potential confusion about whether a patient’s agent may obtain a patient’s medications from an APDS.

Orientation to Use of APDS

The proposed update to 16 CCR 1713(e)(5) effectively harmonizes the regulation with the requirements of BPC 4427.6(a)(5) that participating patients must be “oriented” on the use of the APDS. We suggest that it might be of value to provide guidance to the regulated public on the content of and manner in which to provide orientation to patients on the use of the APDS. This guidance could be added to the regulation or provided in the form of a Board-produced “frequently asked question” document. We suggest that, for many patients, providing orientation using the two-way video interface of the APDS during the first use of the APDS device would be a reasonable approach.

ADDS Self-Assessment Feedback

The software of some APDS devices includes a feature that would allow patients to electronically execute a consent—as required by BPC 4427.6(b)—to receive prescribed drugs from the APDS. It is now commonplace to provide electronic signatures for many types of documents (e.g. financial documents); therefore, many patients are familiar with the mechanics of providing an electronic signature and might even prefer electronically signing the required consent. Therefore, we suggest that question 5.14 of the ADDS Self-Assessment (page 13) should be updated to read “The APDS may only be used for patients who have ~~signed~~ ~~executed~~ a written ~~or~~ ~~electronic~~ consent demonstrating their informed consent to receive prescribed drug and devices from the APDS”.

Additionally, in order to eliminate potential uncertainty about the locations where ADDS devices may be deployed, Kaiser Permanente recommends the following technical modifications to the ADDS Self-Assessment:

1. **Page 6:** Change the text of the checkbox that reads “ADDS adjacent to the secured pharmacy area and Medical Offices” to “ADDS adjacent to the secured pharmacy area ~~and~~ ~~or~~ ~~located in~~ Medical Offices”.

2. **Page 13:** Change the text of the header that reads “SECTION 5: ADDS ADJACENT TO SECURED PHARMACY AREA AND IN MEDICAL OFFICES” to “SECTION 5: ADDS ADJACENT TO SECURED PHARMACY AREA ~~AND~~ OR LOCATED IN MEDICAL OFFICES”.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board’s regulations pertaining to ADDS devices. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.658.3501; rebecca.l.cupp@kp.org).

Respectfully submitted,



John P. Gray, PharmD, MSL
Director, National Pharmacy Regulatory and Government Affairs
Kaiser Permanente

2. Board staff prepared
summarized comments with
recommendations



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2720 Gateway Oaks Drive, Ste 100
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



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

Summarized 45-day Comments Regarding ADDS with Board Staff Recommendations:

Written Comments from BJ Bartleson, California Hospital Association

Comment 1: The commenter recommends that Section 1711 subdivision (f) be amended to read “Further, any record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.” The commenter indicates that without the use of the term “licensed” the regulation could be interpreted to require the submission of quality assurance reports by General Acute Care Hospitals, which are exempt from licensure.

Response to Comment 1: Board staff recommend that this comment be accepted with respect to reporting submitted QA records to the Board within 30 days for licensed ADDS devices. This change is reflected in staff’s recommended text to include the word “licensed.” Further, as Business and Professions Code section 4427.8(b)(1) requires the Board to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS, Board staff recommend that QA completed on unlicensed ADDS devices be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the Board will ensure that the Board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the Board can revisit and determine if this data is still necessary for the Board to monitor and track. Board staff have prepared recommended language that is included in the meeting material packet for this agenda item.

Comment 2: The commenter recommends that Section 1711 subdivision (f) be amended to read “Further, any licensee with a record related to the use of an automated drug delivery system, must also notify the board during license renewal if any quality assurance records related to the use of the APDS were generated ~~be submitted to the board within 30 days of completion of the quality assurance review.~~ The commenter indicates that notifying the Board at the time of renewal of quality assurance records for APDS could be easily done as opposed to submitting the records to the Board within 30 days.

Response to Comment 2: Board staff recommend that this comment be rejected. As mentioned in the response to comment one, the Board is mandated to report to the legislature on or before

January 1, 2024 on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The reporting requirement established in BPC section 4427.8 applies to all ADDS devices used within the health care system and is not specific to only APDS devices. Further, timely receipt and review of QA reports will allow the Board to appropriately monitor for patient safety concerns that could be identified through the timely review of the reports.

Comment 3: The commenter recommends that Section 1713(d)(2) be amended to add “to the patient or patient’s agent” to the end of the subdivision for consistency with Business and Professions Code section 4427.6(c).

Response to Comment 3: Board staff recommend that this comment be accepted. This change is included in the staff recommended modified text.

Written Comments from Mark Johnston, CVS Health

Comment 1: The commenter expressed concern that the changes proposed in Section 1711(f) are unclear and create an undue burden with respect to the term “any record” and commenter requests clarification on the meaning. Commenter recommends that the language be amended to read “any record related to a medication error associated with the use of an automated....” for clarity. Commenter indicates that numerous reports exist that are not relevant and have no bearing on the quality assurance review.

Response to Comment 1: Board staff recommend that this comment be rejected. The quality assurance review identified in this regulation is specific to medication errors, as such, Board staff do not believe adding in a medication error is necessary; however, Board staff recommend amending the language to read “Any quality assurance record related....” for clarity and this change is included in the staff recommended modified text

Written Comments from Michael Tou, Providence St. Joseph Health

Comment 1: The commenter recommends that Section 1711(f) be amended to read “Further, any record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.” Commenter indicates that the regulation is interrupted to apply to licensed ADDS and would exclude AUDES used in hospitals and adding “licensed” clarifies the language.

Response to Comment 1: Board staff recommended that this comment be accepted in part consistent with prior recommendations offered by staff. Further, as the Board is required to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS, Board staff recommend that QA completed on unlicensed ADDS devices be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the Board will ensure that the Board has access to the data necessary to meet the statutorily mandated

reporting. Additionally, following the reporting in 2024, the Board can revisit and determine if this data is still necessary for the Board to monitor and track. Board staff have prepared recommended language that is included in the meeting material packet for this agenda item.

Written Comments from Rita Shane, Cedars-Sinai Medical Center

Comment 1: The commenter recommends that Section 1711(f) be amended to add “This section shall not apply to automated unit dose system located within a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.” Commenter indicates that this addition will exclude AUDES machines used in General Acute Care Hospitals from the quality assurance review process.

Response to Comment 1: Board staff recommend that this comment be accepted in part and rejected in part. As mentioned in response to previous comments, Board staff recommend that licensed ADDS should report to the Board QA records within 30 days so that the Board can track these medication errors more routinely, while balancing the need to also collect additional information for unlicensed ADDS. As indicated in the staff recommended text, board staff recommend that QA completed on unlicensed ADDS devices be reported at the time of the annual renewal of the corresponding facility license. Such an approach will allow the Board to review for patient safety issues and also ensure the Board is positioned to prepare and report to the legislature on or before January 1, 2024 as required. BPC section 4427.8 establishes the requirement for the Board to submit a report on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The legislative report requirement does not draw a distinction between licensed and unlicensed ADDS. This annual reporting to the Board will ensure that the Board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the Board can revisit and determine if this data is still necessary for the Board to monitor and track. Board staff have prepared recommended language that is included in the meeting material packet for this agenda item.

Comment 2: The commenter recommends that Section 1715.1 be amended to add a statement that “This section shall not apply to automated unit dose system located within a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.” The commenter states that the hospital self-assessment includes an ADDS section currently for hospitals to review.

Response to Comment 2: Board staff recommend that this comment be rejected. The ADDS self-assessment applies to all ADDS devices. Hospitals would need to complete the appropriate sections of the ADDS self-assessment consistent with the provisions of this regulation and CCR Section 1715. Board staff recommend that the hospital self-assessment be updated in the future to remove the ADDS portion. As ADDS devices will now have their own self-assessment, duplicating the information within the hospital self-assessment will no longer be needed.

Written Comments from John Gray, Kaiser Permanente

Comment 1: The commenter recommends that Section 1711(f) be amended to clarify if a general acute care hospital would be required to submit quality assurance records.

Response to Comment 1: Board staff recommend that this comment be rejected. As indicated in the staff recommended text, staff’s recommendation provides different reporting requirements for ADDS depending on the licensure status. As mentioned in response to previous comments, Board staff recommend that licensed ADDS should report to the Board QA records within 30 days so that the Board can track these medication errors. Further, as the Board is required to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS, Board staff recommend that QA completed on unlicensed ADDS devices be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the Board will ensure that the Board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the Board can revisit and determine if this data is still necessary for the Board to monitor and track. Board staff have prepared recommended language that is included in the meeting material packet for this agenda item.

Comment 2: The commenter recommends that Section 1711(f) be amended to allow for the disclosure of quality assurance records at the time of renewal as opposed to the record keeping burden associated with submitting the records within 30 days of completing the review. This will ensure that the Board is notified of errors and eliminate the need to report for AUDS devices.

Response to Comment 2: Board staff recommend that this comment be rejected. As mentioned in the response to comment one, the Board is mandated to report to the legislature on or before January 1, 2024 on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. This requirement is specific to all ADDS devices used within the health care system and does not exempt AUDS devices. Staff notes that reporting timeframes vary based primarily on the licensure status of the ADDS.

Comment 3: The commenter recommends that Section 1713(d)(2) be amended to add “to the patient or patient’s agent” to the end of the subdivision for consistency with Business and Professions Code section 4427.6(c).

Response to Comment 3: Board staff recommend that this comment be accepted. This change is included in the staff recommended modified text.

Comment 4: The commenter recommends that a FAQ be developed with respect to Section 1713(e)(5) on the content and manner in which patients be provided orientation on the use of a APDS.

Response to Comment 4: Board staff recommend that this comment be rejected. As not every pharmacy will have the same device or the same business model, Board staff believe that the

pharmacy will need to develop the policies and procedures that are specific to their device and its practice.

Comment 5: The commenter recommends that the self-assessment be amended on page 6 and page 13 to state “or located in a Medical office” instead of “and” for grammatical clarity. Additionally, commenter recommends that page 13 be amended to allow electronic consent for the use of an APDS and change the term “signed” to “executed” for electronic consent.

Response to Comment 5: Board staff recommend that this comment be accepted in part to accept the digital signature and rejected in part. The changes to “or located in a medical office” are accepted. The proposed change to page 13 of the Self-Assessment Form is rejected. Patients who have provided informed consent are eligible for inclusion in receiving prescription drugs via APDA. The signed written consent required under BPC section 4427.6(b) can be satisfied by a digital signature that is retained as part of the patient’s record.

3. Board staff recommended modified text

**California State Board of Pharmacy
Department of Consumer Affairs
California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 17. Board of Pharmacy
Proposed Regulation**

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

Modified changes to the current proposed regulation text are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Amend section 1711 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1711. Quality Assurance Programs.

- (a) Each pharmacy shall establish or participate in an established quality assurance program ~~which~~ that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
- (b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
- (c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
- (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
 - (A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
 - (B) Communicate to the prescriber the fact that a medication error has occurred.
- (3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
- (4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. 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. All medication errors discovered shall be subject to a quality assurance review.

- (e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
- (1-) ~~1-~~ The date, location, and participants in the quality assurance review;
 - (2-) ~~2-~~ The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
 - (3-) ~~3-~~ The findings and determinations generated by the quality assurance review; and,
 - (4-) ~~4-~~ Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. ~~Further, a~~ Any quality assurance record related to the use of an licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal.
- (g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
- (h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Note: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125; and 4427.7, Business and Professions Code.

Amend section 1713 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

- (a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

- (b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
- (c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
- (d) A pharmacy may use an automated patient dispensing system (APDS) delivery device to deliver ~~previously dispensed~~ prescription medications to patients provided:
- ~~(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.~~
 - ~~(2)~~(1) A pharmacist has determined that each patient using the ~~device~~ APDS meets inclusion criteria for use of the APDS device established by the pharmacy prior to delivery of prescription medication to that patient.
 - ~~(3)~~(2) The APDS device has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.
 - ~~(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).~~
 - ~~(5)~~(3) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
 - ~~(6) The device is located adjacent to the secure pharmacy area.~~
 - ~~(7) The device is secure from access and removal by unauthorized individuals.~~
 - ~~(8) The pharmacy is responsible for the prescription medications stored in the device.~~
 - ~~(9)~~(4) Any incident involving the APDS device 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.
 - ~~(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).~~
- (e) Any pharmacy making use of an APDS automated delivery device as permitted by ~~subdivision (d)~~ shall maintain, and on an annual basis review, written policies and procedures providing for:
- (1) Maintaining the security of the APDS automated delivery device and the dangerous drugs within the APDS device.
 - (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS device and for which patients, including when consultation is needed.
 - (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS automated delivery device.
 - (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS automated delivery device.

- (5) Orienting participating patients on use of the APDS automated delivery device, notifying patients when expected prescription medications are not available in the APDS device, and ensuring that patient use of the APDS device does not interfere with delivery of prescription medications.
- (6) Ensuring the delivery of medications to patients in the event the APDS device is disabled or malfunctions.
- (f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS automated delivery device.
- ~~(g) For the purposes of this section only, "previously dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.~~

Note: Authority cited: Sections 4005, 4075, and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, and 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7, and 4427.8, Business and Professions Code

Add section 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 shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
 - (1) A new automated drug delivery system license has been issued.
 - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.
 - (3) There is a change in the licensed location of an automated drug delivery system to a new address.
- (c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) 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 completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink 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 has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system’s license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink 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.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, and 4427.5, Business and Professions Code and 16.5, Government Code.



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



AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

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

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

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

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

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

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

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

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS** – “Automated drug delivery system,” a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

- 1.1. The pharmacy uses an **APDS** – “Automated **PATIENT** dispensing system,” an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]
- 1.2 The pharmacy uses an **AUDS** – “Automated **UNIT DOSE** system,” an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]
- 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 States Code. [BPC 4119.11(a)-(a)(11)]
- 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

Yes No N/A

- 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]
- 2.4 Provides pharmacy services through **a clinic** licensed pursuant to section 1204 or 1204.1 of the Health and Safety Code, or section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3]]
- 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]
- 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]
- 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

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

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

- 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]
- 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]
- 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]
- 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]
- Use of the ADDS is consistent with legal requirements.
 - The proposed location for installation of the ADDS met the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
 - The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

- The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

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

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

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

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

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

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

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

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

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

Yes No N/A

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

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

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

- SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- SECTION 5 – ADDS adjacent to the secured pharmacy area ~~and~~ or located in Medical Offices.
- SECTION 6 – ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6 (LTC).
- SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- SECTION 8 – ADDS operated by a correctional clinic.
- SECTION 9 - AUDES used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (when the hospital pharmacy is closed and no pharmacist is available).

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 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]
- 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]
- 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

Date of Inspection: _____

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

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

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

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

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____
 9. _____ 10. _____
 11. _____ 12. _____
 13. _____ 14. _____
 15. _____

Yes No N/A

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

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

Date of Last Self-Assessment: _____

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

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

4.18 The underlying operating pharmacy is solely responsible for:

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

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

- 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]
 - 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]
 - 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2)]
 - 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

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

Date of Last Review: _____

- 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]
 - All controlled substances added to the ADDS/APDS are accounted for;
 - Access to ADDS/APDS is limited to authorized facility personnel;
 - An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
 - Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. DEVICE REQUIREMENTS

Yes No N/A

- 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]
- 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]
- 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]
- 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]
- 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]
- 4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]
- Maintaining the security of the APDS and dangerous drug and devices within the APDS
 - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
 - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
 - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
 - Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

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

Yes No N/A

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

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

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

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

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

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

F. POLICIES AND PROCEDURES

Yes No N/A

- 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:
- Maintaining the security of the APDS and dangerous drug and devices within the APDS
 - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
 - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
 - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

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

Date of Last Policy Review: _____

Yes No N/A

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

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

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

A. GENERAL REQUIREMENTS

Yes No N/A

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

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

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

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

Yes No N/A

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

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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. 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)]

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

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

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

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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)]

Yes No N/A

- 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)]
- 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]
- 5.15 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]
- 5.16 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]
- 5.17 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]
- 5.18 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]
- 5.19 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]
- 5.20 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 5.21 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]
- 5.22 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 5.23 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 5.24 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. POLICIES AND PROCEDURES

Yes No N/A

- 5.28 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]
 - Maintaining the security of the APDS and dangerous drug and devices within the APDS
 - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
 - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
 - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
 - Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

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

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

A. GENERAL REQUIREMENTS

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

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

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

- 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]
- 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]
- 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]
- 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]
- 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]
- 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]
- 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

- 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]
- All controlled substances added to the ADDS are accounted for;
 - Access to ADDS is limited to authorized facility personnel;
 - An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
 - Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

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

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. DEVICE REQUIREMENTS:

Yes No N/A

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

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

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

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

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

Yes No N/A

6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

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

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

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

Yes No N/A

- 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]
- 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]
- 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]
- 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]
- 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]
- 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]
- 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]
- 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. POLICIES AND PROCEDURES

Yes No N/A

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

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

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

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

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

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

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

A. GENERAL REQUIREMENTS

Yes No N/A

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

License number: _____ Expiration Date: _____

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

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

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

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

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

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

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

Yes No N/A

- 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule 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.
- 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]
- 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]
- 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]
- 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 7.14 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
- 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

Yes No N/A

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

7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]

List of current APDS licenses:

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. PHARMACIST RESPONSIBILITY

Yes No N/A

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

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

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

Date of Last Review: _____

Yes No N/A

- 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]
- 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]
- 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]
- 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]
- 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]
- 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]
- 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. POLICIES AND PROCEDURES

Yes No N/A

- 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]
 - Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
 - Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.

- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

- 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]
- 7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]
- 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]
- 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

- 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]
- 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Code, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

Yes No N/A

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

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

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

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. POLICIES AND PROCEDURES

Yes No N/A

- 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]
- 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]
- 8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]
- 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]
- 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]
- 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]
- 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]
- 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

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

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

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

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. DEVICE REQUIREMENT

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

SECTION 9: AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)

A. GENERAL REQUIREMENTS

Yes No N/A

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 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)]

Yes No N/A

9.2 The prescriber in a hospital emergency room dispenses drug from the AUDS when the hospital pharmacy is closed and there is no pharmacist available in the hospital. The drugs is acquired by the hospital pharmacy. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens. The hospital pharmacy retains the dispensing information. 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 at the time of dispensing to the patients. 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)(2)(3)(4)(5)(6)]

9.3 The prescriber ensures the label on the drug contains all the information required by BPC 4076, CCR 1707.5

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

9.5 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 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 4069(a)(4), HSC 11165(d)]

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

9.8 The hospital has written policies and procedures to ensure each patient receive 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)]

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)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____ Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____ Date _____

4. The proposed text
released for 45-day public
comment.

**Title 16. Board of Pharmacy
Proposed Regulation**

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

Amend section 1711 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1711. Quality Assurance Programs.

- (a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
- (b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
- (c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
- (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
 - (A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
 - (B) Communicate to the prescriber the fact that a medication error has occurred.
- (3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
- (4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. 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. All medication errors discovered shall be subject to a quality assurance review.
- (e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

- ~~(1.)~~ ~~The date, location, and participants in the quality assurance review;~~
- ~~(2.)~~ ~~The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);~~
- ~~(3.)~~ ~~The findings and determinations generated by the quality assurance review;~~
and,
- ~~(4.)~~ ~~Recommend changes to pharmacy policy, procedure, systems, or processes, if any.~~

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.
- (g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
- (h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Note: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125, and 4427.7, Business and Professions Code.

Amend section 1713 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

- (a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
- (b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
- (c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
- (d) A pharmacy may use an automated patient dispensing system (APDS) delivery device to deliver ~~previously dispensed~~ prescription medications to patients provided:

- ~~(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.~~
- ~~(2)(1) A pharmacist has determined that each patient using the device APDS meets inclusion criteria for use of the APDS device established by the pharmacy prior to delivery of prescription medication to that patient.~~
- ~~(3)(2) The APDS device has a means to identify each patient and only release that patient's prescription medications.~~
- ~~(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).~~
- ~~(5)(3) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.~~
- ~~(6) The device is located adjacent to the secure pharmacy area.~~
- ~~(7) The device is secure from access and removal by unauthorized individuals.~~
- ~~(8) The pharmacy is responsible for the prescription medications stored in the device.~~
- ~~(9)(4) Any incident involving the APDS device 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.~~
- ~~(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).~~
- (e) Any pharmacy making use of an APDS automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:
 - (1) Maintaining the security of the APDS automated delivery device and the dangerous drugs within the APDS device.
 - (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS device and for which patients, including when consultation is needed.
 - (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS automated delivery device.
 - (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS automated delivery device.
 - (5) Orienting participating patients on use of the APDS automated delivery device, notifying patients when expected prescription medications are not available in the APDS device, and ensuring that patient use of the APDS device does not interfere with delivery of prescription medications.
 - (6) Ensuring the delivery of medications to patients in the event the APDS device is disabled or malfunctions.
- (f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS automated delivery device.
- ~~(g) For the purposes of this section only, "previously dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been~~

~~previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.~~

Note: Authority cited: Sections 4005, 4075, and 4114, Business and Professions Code.
Reference: Sections 4005, 4017.3, 4052, 4116, ~~and 4117~~, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7, and 4427.8, Business and Professions Code

Add section 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 shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
- (1) A new automated drug delivery system license has been issued.
 - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.
 - (3) There is a change in the licensed location of an automated drug delivery system to a new address.
- (c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) 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 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 completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink on the self-assessment form.
- (6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system’s license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink on the self-assessment form.
- (d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. 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.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code.
Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, and 4427.5, Business and Professions Code.



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



AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

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

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

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

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

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

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

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

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS** – “**Automated drug delivery system**,” a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

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

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

SECTION 2: LOCATION OF DEVICES

Yes No N/A

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

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

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

Yes No N/A

- 2.4 Provides pharmacy services through a **clinic** licensed pursuant to section 1204 or 1204.1 of the Health and Safety Code, or section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3]
- 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]
- 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]
- 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

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

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

- 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]
- 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]
- 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]
- 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]
- Use of the ADDS is consistent with legal requirements.
 - The proposed location for installation of the ADDS met the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
 - The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
 - The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

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

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

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

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

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

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

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

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

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

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

Yes No N/A

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

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

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

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

A. GENERAL REQUIREMENTS

Yes No N/A

- 4.1 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 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]
- 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]
- 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]
- 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

Date of Inspection: _____

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

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

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

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

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

Yes No N/A

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

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

Date of Last Self-Assessment: _____

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

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

4.18 The underlying operating pharmacy is solely responsible for:

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

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

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

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

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

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

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

Date of Last Review: _____

- 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]
 - All controlled substances added to the ADDS/APDS are accounted for;
 - Access to ADDS/APDS is limited to authorized facility personnel;
 - An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
 - Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. DEVICE REQUIREMENTS

Yes No N/A

- 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]
- 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]
- 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]
- 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]
- 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]
- 4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]
- Maintaining the security of the APDS and dangerous drug and devices within the APDS
 - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
 - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
 - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
 - Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

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

Yes No N/A

- 4.27.3 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3)]
- 4.27.4 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]
- 4.27.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]
- 4.27.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]
- 4.27.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]
- 4.27.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]
- 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]
- 4.28 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 4.29 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
- 4.30 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 4.31 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

F. POLICIES AND PROCEDURES

Yes No N/A

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

Date of Last Policy Review: _____

Yes No N/A

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

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

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

A. GENERAL REQUIREMENTS

Yes No N/A

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

- 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]
- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
 - Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
 - Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.
 - Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
 - Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

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

- 1. _____ 2. _____
- 3. _____ 4. _____
- 5. _____ 6. _____
- 7. _____ 8. _____
- 9. _____ 10. _____
- 11. _____ 12. _____
- 13. _____ 14. _____
- 15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

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

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

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

Yes No N/A

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

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

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

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. DEVICE REQUIREMENTS:

Yes No N/A

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

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

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

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

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

Yes No N/A

- 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]
- 5.15 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]
- 5.16 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]
- 5.17 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]
- 5.18 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]
- 5.19 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]
- 5.20 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 5.21 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]
- 5.22 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 5.23 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 5.24 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. POLICIES AND PROCEDURES

Yes No N/A

- 5.28 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]
 - Maintaining the security of the APDS and dangerous drug and devices within the APDS
 - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
 - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
 - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
 - Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

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

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

A. GENERAL REQUIREMENTS

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

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

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

- 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]
- 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]
- 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]
- 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]
- 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]
- 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]
- 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

- 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]
- All controlled substances added to the ADDS are accounted for;
 - Access to ADDS is limited to authorized facility personnel;
 - An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
 - Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

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

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. DEVICE REQUIREMENTS:

Yes No N/A

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

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

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

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

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

Yes No N/A

6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

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

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

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

Yes No N/A

- 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]
- 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]
- 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]
- 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]
- 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]
- 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]
- 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]
- 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. POLICIES AND PROCEDURES

Yes No N/A

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

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

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

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

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

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

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

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

A. GENERAL REQUIREMENTS

Yes No N/A

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

License number: _____ Expiration Date: _____

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

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

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

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

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

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

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

Yes No N/A

- 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule 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.
- 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]
- 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]
- 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]
- 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 7.14 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
- 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

Yes No N/A

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

7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]

List of current APDS licenses:

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

7. _____ 8. _____

9. _____ 10. _____

11. _____ 12. _____

13. _____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. PHARMACIST RESPONSIBILITY

Yes No N/A

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

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

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

Date of Last Review: _____

Yes No N/A

- 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]
- 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]
- 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]
- 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]
- 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]
- 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]
- 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. POLICIES AND PROCEDURES

Yes No N/A

- 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]
 - Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
 - Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
 - Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.

- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

- 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]
- 7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]
- 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]
- 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

- 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]
- 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Code, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

Yes No N/A

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

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

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

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

B. POLICIES AND PROCEDURES

Yes No N/A

- 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]
- 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]
- 8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]
- 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]
- 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]
- 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]
- 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]
- 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

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

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

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

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

D. DEVICE REQUIREMENT

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

E. RECORD KEEPING REQUIREMENTS

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE _____

CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____ Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

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

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____ Date _____