

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

### **Background:**

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

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on November 11, 2022, which ended on December 27, 2022. Several comments were received during the comment period and, following review by the Board at the February 2023 Board meeting, amended language was released for 15-day public comment.

The 15-day public comment period began on February 10, 2023 and ended on February 25, 2023. Several comments were received during the comment period. Attached following this memo are the following:

- 1. The proposed text released for the 15-day public comment period.
- 2. Board staff prepared summarized comments with recommendations.
- 3. Board staff recommended modified text.
- 4. Comments received during the 15-day comment period.

#### 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 on February 10, 2023.
- 2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a second 15-day comment period.

### **Possible Adoption Language:**

Accept the Board staff recommended comment response, approve the staff recommended proposed text, and initiate a second 15-day public comment period. Additionally, if no adverse comments are received during the second 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at

Section 1715.1. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

# **Attachment 1**

## Title 16. Board of Pharmacy Proposed Regulation Text

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and <u>underline</u> for added language.

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

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

- (a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  - (1) A new automated drug delivery system license has been issued.
  - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.
  - (3) There is a change in the licensed location of an automated drug delivery system to a new address.
- (c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18223) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  - (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    - (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    - (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
    - (C) DEA registration number, expiration date, and date of most recent DEA inventory;
    - (D) Hours of operation of the pharmacy; and
    - (E) ADDS license number, address, and hours of operation.
  - (2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
  - (3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

- (4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
- (5) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has they have completed the self-assessment of the automated drug delivery system of which he or she is they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
- (6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she they have has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing drug delivery system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.
- (d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
- (e) Any identified areas of noncompliance shall be corrected as specified in the assessment.
- (f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:
  - (1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and
  - (2) The same policies and procedures required by Section 4427.2 of BPC are used.

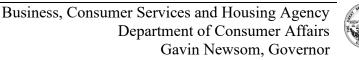
Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.



### 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





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

2023 changes are shown by *italicized double strikethrough* for deleted language and *italicized wavy* underline for added language.

#### **AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT**

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

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

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

Note: For a hospital pharmacy operating an ADDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the ADDS. The hospital pharmacy is required to comply with all other requirements including completing the ADDS Self-Assessment pursuant to BPC 4427.7(a). The PIC may complete a single self-assessment if the mechanical devices used are the same and the same policies are procedures are used. (CCR 1715.1(a))

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 n	needed, you may add additional sheets.			
Pharmacy Name:				
Address:				
City:	Zip Code:			

	Fax number:			
Website: Pharmacy License #:	Fxpiration	Date:		
DEA Registration #:	DFA Expira	tion Date:		
DEA Inventory Date:				
Pharmacy Hours: M-F:		Sunday		
	ADDS Expirat			
	7:n Codo:			
	Saturday	Zip Code:		
	rs are different than the pharm			
Reason for completing self-asse	<u>essment:</u>			
☐ Performing self-assessment	before July 1 of every odd-num	bered year. [BPC 4427.7, CCR		
1715.1(a)]		_		
☐ Completing a self-assessme	nt within 30 days when a new A	DDS license was issued. [BPC		
4427.7, CCR 1715.1(b)(1)]	•	<del></del>		
· · · · · · · · · · · · · · · · · · ·	nt within 30 days when there wa	as a change in PIC. [BPC		
4427.7, CCR 1715.1(b)(2)]		<u> </u>		
· · · · · · · · · · · · · · · · · · ·	nt within 30 days when there w	as a change in the licensed		
-	☐ Completing a self-assessment within 30 days when there was a change in the licensed location of an ADDS to a new address. [BPC 4427.7, CCR 1715.1(b)(3)]			
	10cation of an ADD3 to a new address. [b] C 4427.7, CCN 1713.1[b](3]]			
FOR ALL TYPES OF ADDS: CON	1PLETE SECTIONS 1, 2 AND 3			
SECTION 1: DEFINITIONS/TYPE	E OF ADDS DEVICE USED			
An ADDS – "Automated drug d	lelivery system," a mechanical s	ystem that performs operatior		
or activities other than compou	unding or administration, relative	e to storage, dispensing, or		
distribution of drugs. An ADDS	, shall collect, control, and main	tain all transaction information		
	ent of drugs into and out of the			
and accountability. [BPC 4119.2	_	, , , , , , , , , , , , , , , , , , , ,		
IDENTIFY THE TYPE OF ADDS D	EVICE USED			
o N/A				
	OS – "Automated PATIENT dispe			
	cribed drugs directly to the patie	ents pursuant to prior		
authorization by a pharmacist.	[BPC 4119.11(b)(2), 4017.3(c)]			
1.2 The pharmacy uses an AUDS	S – "Automated UNIT DOSE svst	em," an ADDS for the storage		
	s for administration to patient by	_		
these functions. [BPC 4119.11(l		, persons additionized to periori		
17M 117 (Day 12/18722)	Page 2 of 4E	DIC Initials		
<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> <u>2€3</u> )	Page 2 of 45	PIC Initials		

	1.3 The pharmacy uses an <b>AUDS – "Automated UNIT DOSE system</b> ," 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 <u>covered entities</u> , as defined that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by section 256b of Title 42 of United Sates Code. [BPC 4119.11(a) <del>-(a)(11)</del> ]
	2.2 Provides pharmacy services through an <u>ADDSAPDS</u> <u>adjacent to the secured pharmacy area</u> of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]
Ves No N/4	2.3 Provides pharmacy services through an ADDS in a health facility licensed pursuant to section 1250 of the Health and Safety Code (HSC)(Long Term Care (LTC)) that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2), HSC 1250, HSC 1261.6]
	2.4 Provides pharmacy services through <u>an AUDS in</u> <u>a clinic</u> 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 <b>correctional clinic</b> . [BPC 4187.1, 4427.3(b)(4)]
	2.6 Provides pharmacy services through a <u>medical office</u> or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.3(b)(5), 4427.6(j)]
	2.7 <u>AUDS operated by a licensed hospital pharmacy</u> , as defined in section 4029 <u>of the Business and Professions Code</u> , 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 <u>of the Business and Professions Code</u> . The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC 4427.2(i)]

Page 3 of 45

PIC Initials \_\_\_\_\_

	2.8 AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room), as				
	defined in section 4056 of the Business and Professions Code, and is used to provide doses				
	administered to patients while in a licensed general acute care hospital and to dispense drugs				
	to outpatients if the physician determines that it is in the best interest of the patient that a				
	particular drug regimen be immediately commenced or continued, and the physician				
	reasonably believes that a pharmacy located outside the hospital is not available and accessible				
	at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical				
	services or within a 30-mile radius. The quantity dispensed is limited to an amount necessary				
Yes No N/A	to maintain uninterrupted therapy and does not exceed a 72-hour supply. [BPC 4056, 4427.2(i)]				
	2.9 AUDS located in the emergency room operated by a licensed hospital pharmacy, as defined				
	in subdivisions (a) and (b) of section 4029 of the Business and Professions Code, and is used to				
	provide doses administered to patients while in a licensed general acute care hospital facility or				
	a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of section				
	1250 of the Health and Safety Code, and to dispense to an emergency room patient if: [BPC				
	4068, 4427.2(i)]				
	2.9.1. The hospital pharmacy is closed and there is no pharmacist available in the				
	hospital.				
	<ul><li>2.9.2. The drug is acquired by the hospital pharmacy.</li></ul>				
	<ul> <li>2.9.3. The dispensing information is recorded and provided to the pharmacy when the</li> </ul>				
	pharmacy reopens.				
	<ul> <li>2.9.4. The hospital pharmacy retains the dispensing information and controlled</li> </ul>				
	substances dispensing information is reported to the Department of Justice pursuant to				
	section 11165 of the Health and Safety Code.				
	<ul> <li>2.9.5. The prescriber determines it is in the best interest of the patient that a particular</li> </ul>				
	drug regimen be immediately commenced or continued and the prescriber reasonably				
	believes a pharmacy located outside the hospital is not available and accessible at the				
	time of dispensing to the patient.				
	2.9.6. The quantity is limited to an amount necessary to maintain uninterrupted				
	therapy, but shall not exceed a 72-hour supply.				
	Note: Licensure of AUDS operated under these provisions is required.				
	2.10 A facility licensed in CA with the statutory authority to provide pharmaceutical services.				
	[BPC 4427.65(a)(1)]				
	Type of Facility:				
	Statutory authority to provide pharmaceutical services (List code section):				
	<u>Statutory authority to provide pharmaceutical services (List code section).</u>				
	2.11 Jail, youth detention facility, or other correctional facility where drugs are administered				
	within the facility under the authority of the medical director. [BPC 4427.3(b)(6), BPC				
	4427.65(a)(2)]				
	Type of Facility:				
	Statutory authority for type of Facility (List code section):				
	estate y an array for type or r domey take bodie bodie in				

Page 4 of 45

PIC Initials \_\_\_\_\_

<u>Please</u> Note: An ADDS license is not required for technology, installed <u>within the secured</u> <u>licensed premises area of a pharmacy,</u> 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  $\square$  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)]  $\square$   $\square$   $\square$  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)]  $\square$  3.4.1 Use of the ADDS is consistent with legal requirements.  $\square$  3.4.2 The proposed location for installation of the ADDS meets the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. security measures and monitoring of the inventory to prevent theft and diversion. ☐ 3.4.4 The pharmacy's policy and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. Yes No N/A  $\square$   $\square$  3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)] List date<del>(s)</del> of pre-license inspection<del>(s)</del>:  $\square$  3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]  $\square$   $\square$  3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]  $\square$  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

Page 5 of 45

PIC Initials

board. [BPC 4427.2(f)]

	3.9 The pharmacy is aware the holder of a 30 days if use of an ADDS is discontinued.		board in writing within
	3.10 The ADDS license(s) is/were renewed underlying pharmacy license. [BPC 4427.2]		te is the same as the
	3.11 The ADDS is placed and operated insi location approved by the board. [BPC 442		a premises address, at a
Yes No N//	3.12 Prior to installation, the pharmacy ho ADDS is placed pursuant to subdivision (be jointly developed and implemented writt accountability, security, patient confident quality, potency, and purity of the drugs a maintained at the location of the ADDS at [BPC 4427.3(c)]	o) of Business and Professions en policies and procedures to tiality, and maintenance of the and devices. The policies and	Code section 4427.3, ensure safety, accuracy, e ADDS, as well as procedures are
	<ul><li>3.13 Each ADDS is operated under the sup [BPC 4427.4(b)]</li><li>3.14 The ADDS is considered an extension regardless of the ADDS location, and is su [BPC 4427.4(c)]</li></ul>	and part of the pharmacy hol	ding the ADDS license,
Yes No N/s	3.15 Drugs and devices stored in an ADDS responsibility of the pharmacy holding th from the ADDS shall be considered to have 4119.11(a)(3)	e ADDS license, and the drugs	and devices dispensed
	3.16 The stocking and restocking of an AD technician or intern pharmacist under the located in a health facility pursuant to HS ADDS may be performed in compliance w	e supervision of a pharmacist, C 1250, where the stocking ar	except for an ADDS and restocking of the
	3.17 Access to the ADDS is controlled and biosensor. [BPC 4427.4(e)(2), 4427.65(c)(	_	n or password system or
	3.18 The ADDS makes a complete and accacessing the system and all drugs added BPC 4427.65(c)(5)(D), BPC 4119.11(f), HSG	to, or removed from, the syst	_
	3.19 Are drugs or devices not immediately location, stored for no longer than 48 hou	•	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 6 of 45	PIC Initials

	approved by the board under section 4427.3 of the Business and Professions Code, and, upon retrieval of the dangerous drugs and dangerous devices from the secured storage, is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]
	3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]
Yes No N/A	3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.  [BPC 4427.7(b), BPC 4427.7(b), BPC 4119.11(j)]
	3.22 The record of quality assurance review, as provided in California Code of Regulation section 1711(e), is immediately retrievable in the pharmacy for at least one year from the date the record was created. [CCR 1711(f)]
	3.23 An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the pharmacy's license. [CCR 1711 (e), CCR 1711(f)]
	3.24 The PIC of EACH ADDS completes a self-assessment of the pharmacy's compliance with  federal and state pharmacy law and is performed [CCR 1715.1(a), (b)]:  Before July 1 of every odd-numbered year.  Within 30 days whenever a new ADDS licensed has been issued.
	<ul> <li>Within 30 days when there is a change in PIC.</li> <li>When there is a change in the licensed location of an ADDS to a new address.</li> </ul>
	3.25 The PIC of an ADDS assesses the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1/22) entitled "Automated Drug Delivery System Self-Assessment." [CCR 1715.1(c)]
	3.26 The PIC responds "yes", "no", or "not applicable" about whether the ADDS is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting. [CCR 1715.1(c)(2)]
	3.27 For each "no" response, the PIC provides a written corrective action or action plan to come into compliance with the law. [CCR 1715.1(c)(3)]

	3.28 The PIC initialed each page of the self-assessment with original handwritten initials in ink or
	digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form.
	<del>[CCR 1715.1(c)(4)]</del>
	2.30 The DIC has contified as the last areas of the colf accessored that they are the DIC has
	3.29 The PIC has certified on the last page of the self-assessment that they are the PIC, has
	certified a timeframe within which any deficiency identified within the self-assessment will be
	Corrected, and has acknowledged all responses are subject to verification by the Board of
	<u>Pharmacy. The certification is made under penalty of perjury of the laws of the State of</u>
	<u>California and the information provided in the self-assessment form is true and correct with an</u>
	original handwritten signature in ink or digitally signed in compliance with Civil Code Section
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	1633.2(h) on the self-assessment form. [CCR 1715.1(c)(5)]
Yes No N/A	3.30 The ADDS owner has certified the final page of the self assessment that they have read and
	reviewed the completed self-assessment and acknowledges that failure to correct any deficiency
	identified in the self-assessment could result in the revocation of the ADDS license issued by the
	Board. The certification is made under penalty of perjury of the laws of the State of California
	with an original handwritten signature or digitally signed in compliance with Civil Code Section
	1633.2(h) on the self-assessment form. [CCR-1715.1(c)(6)]
	3.31 Each self-assessment is completed in its entirety and kept on file in the underlying pharmac
	for three (3) years after it is performed. The completed, initialed, and signed original is readily
	available for review during any inspection by the Board. [CCR 1715.1(d)]
	3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.
	[CCR 1715.1(e)]
	3.33 The PIC ensures the following: [CCR 1715.65(h)]
	<u> ∃-3.33.1 All controlled substances added to an ADDS are accounted for.</u>
	= 3.33.2 Access to the ADDS is limited to authorized facility personnel.
	= 3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled
	substances is performed.
	======================================
	= <u>9.99.7 conjunica 1933es of controlled Substance dre reported to the bodia.</u>
	3.24 The pharmacy's inventory reconciliation report prepared at least once every three months
<b></b>	for federal Schedule II controlled substances, includes the federal Schedule II controlled
	substances stocked in the ADDS. (CCR 1715.65[a][1])
	annatures atocked in the UDDA TOOK TATA ON [M][T]]
	3.25 The pharmacy's inventory reconciliation report prepared at least once every 12 months for
	alprazolam 1mg/unit, alprazolam 2mg/unit, Tramadol 50mg/unit and promethazine/codeine
	6.25mg/10mg/5ml, includes these controlled substances stocked in the ADDS. (CCR
	1715.65([a][2])

Page 8 of 45

PIC Initials \_\_\_\_\_

3.26 Inventory activities are performed at least once every two years from the performance of the last inventory activities for each controlled substance that is not listed as a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml and includes the controlled substances stocked in the ADDS. (CCR 1715.65[a][3][B])
3.27 For any controlled substance stocked in the ADDS that is not a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, the pharmacy prepares an inventory reconciliation report for the identified loss of that controlled substance in the ADDS no later than three months after the discovery of the reportable loss and is completed if the loss is discovered either by the inventory activities or any other manner. (CCR 1715.65[a][3][A])
3.28 A physical count, not an estimate, of the federal controlled substances in the ADDS is taken for the inventory reconciliation reports, except for an inpatient hospital pharmacy or correctional pharmacy where the inventory in the ADDS may be accounted for using means other than a physical count. (CCR 1715.65[c][1], CCR 1715.65[h])
3.29 The PIC or the consulting pharmacist for a clinic (BPC 4180 or 4190) reviews all inventory activities performed and inventory reconciliation reports prepared in accordance with CCR 1715.65 and has established and maintained secure methods to prevent losses of federal controlled substances. (CCR 1715.65[b])
3.30 The pharmacy has written policies and procedures developed for performing the inventory activities and preparing the inventory reconciliation reports in accordance with CCR 1715.65 that includes the inventory of federal controlled substances stored in the ADDS. (CCR 1715.65)
3.341 The original board-issued ADDS permit and current renewal are posted at the ADDS premise, where they may be clearly read by the public. [BPC 4058]
CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.
Please Note: The Pharmacist-in-Charge of the pharmacy and the <u>pharmacy</u> owner of the ADDS shall sign the Certification Acknowledgment on page 33 48 after completing the assessment.

Page 9 of 45

PIC Initials \_\_\_\_\_

		SECTION 4: —APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
		SECTION 5 <u>:</u> <del>ADDS</del>
		<ul> <li>APDS adjacent to the secured pharmacy area (or)</li> </ul>
		<u>APDS</u> located in <u>a Medical Offices (or)</u>
		APDS located where patients are regularly seen for purposes of diagnosis and
		treatment to only be used for patients of the practice (or)
		<ul> <li>APDS located at a clinic pursuant to HSC 1204, HSC 1204.1, BPC 4180, or BPC</li> </ul>
		<u>4190.</u>
		SECTION 6: —ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6.
	<del></del> -	1201.0. - <del>SECTION 7 — APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.</del>
		SECTION 87:— ADDS operated by a correctional clinic pursuant to BPC 4187.1,
	=	4427.3(b)(6), or 4427.65(a)(2).
		SECTION <u>98:</u>
		<ul> <li>Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 (when the</li> </ul>
		hospital pharmacy is closed and no pharmacist is available.
		<ul> <li><u>Drug Room:</u> AUDS used for dispensing pursuant to BPC 4056.</li> </ul>
		SECTION 9:
		<ul> <li>AUDS through a facility licensed in California with statutory authority to provide</li> </ul>
		pharmaceutical services (or)
		<ul> <li>AUDS through a jail, youth detention facility, or other correctional facility where</li> </ul>
		drugs are administered within the facility under the authority of the medical
		<u>director pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).</u>
		ON 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND
	MEDIC	CAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY
	Α.	GENERAL REQUIREMENTS
Yes No N/A		
		overed Entity May Contract with Pharmacy to Provide Services. The operating pharmacy
	•	ing pharmacy services to the patients of the covered entity, including, unless prohibited
	•	other law, patients enrolled in the Medi-Cal program, shall be under contract with the d entity as described in BPC section 4126 to provide those pharmacy services through
		e of the APDS. [BPC 4119.11(a)(2)]
	tile ast	5 5
	4.2 Con	tracts between the covered entities and the pharmacy shall comply with the guidelines
		ned by the Health Resources and Services Administration and are available for inspection
	by Boar	rd during normal business hours. [BPC 4126(a)]

	4.3 Drugs purchased and received (USC) shall be segregated from th means. [BPC 4126(b)]	•	
Yes No N//	4.4 All records of acquisition and d separate from the pharmacy's oth		be readily retrievable in a form
	4.5 The drugs shall be returned to be dispensed to patient of a cover distributed because of a change in [BPC 4126(c)]	red entity pursuant to section	256b of Title 42 USC cannot be
	4.6 A licensee that participates in a this section shall not have both a		
	CORRECTIVE ACTION OR ACTION	PLAN AND COMPLETION DATE	
Yes No N//	B. UNDERLYING OPERATING	PHARMACY	
	4.7 The operating pharmacy has ol includes the address of the APDS site. [BPC 4119.11(a)(1)]		•
	4.8 A separate license was obtained concurrent with the pharmacy lice APDS at an address for which the 4119.11(a)(8), 4107]	ense. (Note: The Board may iss	sue a license for operation of an
	4.9 A prelicensure inspection of th 30 days after Board receipt of the	• •	•
	Date of Inspection:		
	4.10 The pharmacy will submit a n current APDS is relocated. [BPC 4:		for Board approval if the
	4.11 The pharmacy will notify the discontinuing an APDS. [BPC 4119	•	ement of an APDS or
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 11 of 45	PIC Initials

	4.12 A new APDS licensure application wi underlying operating pharmacy's permit (Once cancelled, a new APDS license can reissued or reinstated.) [BPC 4119.11(a)(	being cancelled, not currently be issued if the unc	rent, not valid, or inactive.
Yes No N/A	, -	han 15 APDS licenses for	
	1	2	
	3	4	
	5	6	
	7	8	
	9	10	
	11	12	
	13	14	<del>-</del>
	15		
	4.14 The operating pharmacy will mainta after the last date of use for that APDS. [ 4.15 The operating pharmacy of an APDS pursuant to CCR 1715.1 or BPC 4427.7(a law relating to the use of the APDS. [BPC Date of Last Self-Assessment:	BPC 4119.11(d)(11) <u>. CCR</u> has completed a <del>n annua</del> ) evaluating the pharmac (4119.11(i)]	1713(f)]  H biennial Self-Assessment  y's compliance with pharmacy
	Reason: ☐ Biennial; ☐ New ADDS; ☐ C	hange in PIC; ☐ Change	in location of ADDS
	4.16 The operating pharmacy has compliced requirements pursuant to BPC 4119.11 and holding the APDS and separately from the se	and those records will be	maintain within the pharmacy
	4.17 The pharmacy is aware that the drug pharmacy's drug inventory and the drug been dispensed by that pharmacy. [BPC	s dispensed by the APDS	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> <u>2<del>2</del>3</u> )	Page 12 of 45	PIC Initials

	4.1 <u>86</u> The underly	ing operating pharm	nacy is solely responsib	le for: [ <u>BPC 4119.11(a)(5), (6)]</u>
	4.16.2 The op 4.16.3 The m 4.16.4 The tr	aintenance of the Al aining regarding the	5. [BPC 4119.11(a)(5)] PDS. [BPC 4119.11(a)(5	he APDS for both the pharmacy
	CORRECTIVE ACT	ION OR ACTION PLA	N AND COMPLETION D	ATE:
		CIST RESPONSIBILITI	ES	······································
Yes No N/A	4.1 <u>97</u> The operati behalf of the ope	rating pharmacy. [BI	PC 4119.11(a)(7)]. Note	a licensed pharmacist acting on e: The pharmacist need not be the system electronically.
	4.2918 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)]			
	supervision o similar techno 4. <del>20</del> 18.2 Truunit of use or	f the pharmacist ma plogy, or unit of use ansportation of remo	y place drugs into the roor single dose contained oveable pockets, cards are between the pharma	r technician working under the removeable pockets, cards, drawers, ers. [BPC 4119.11(g)(1)], drawers or similar technology of acy and the facility are in a tamper-
	☐ 4. <del>20</del> 18.3 Th drawers, simi	ere are policies and	procedures to ensure	the removeable pockets, cards, e containers are properly placed into
	4.2119 The A pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]			cleanliness of the APDS, and a
	Date of Last Revie	ew:		
	<b>17M-112</b> (Rev. 1	2/ <del>18</del> <u>2<del>2</del>3</u> )	Page 13 of 45	PIC Initials

	4. <del>22</del> 20 The Pharm [CCR 1715.65(h)]	acist-in-charge of the o	offsite ADDS/APDS has ensur	ed the following:
	☐ 4.20.2 Access☐ 4.20.3 An one substa	to ADDS/APDS is limit oing evaluation of disc nce is performed; and	ded to the ADDS/APDS are acted to authorized facility personed to authorized facility personed access are reported to	onnel; associated with controlled
	CORRECTIVE ACTI	ON OR ACTION PLAN A	AND COMPLETION DATE:	
	D. DEVICE RE	QUIREMENTS		
Yes No N/A	4.2 <u>€1</u> Access to the biosensor. System	s tracked via passwor	nd tracked using an identifica d shall include a camera that icture must be maintained fo	records a picture of the
			rate records of all transactio	
	4.2 <u>52</u> The APDS wi	ll collect, control, and	removed from the APDS. [BP6] maintain all transaction info APDS. [BPC 4119.11(c)(1)]	· · -
		and inspection by aut	n information in a readily ava horized individuals for a mini	
	4.2 <u>∓4</u> The APDS ma [BPC 4119.11(d)]	y dispense medicatior	ns <b>DIRECTLY</b> to the patient if	<b>all</b> the following are met:
	policies and p		oped <u>,</u> <del>and</del> implemented <u>, and</u> t to all the following and the <del>F)</del> , CCR 1713(e)	
	<u> </u>	Maintaining the security within the APDS.	rity of the APDS and dangero	us drug and devices
	<b>17M-112</b> (Rev. 1 <del>2</del>	/ <del>18<u>22</u>3</del> )	Page 14 of 45	PIC Initials

	브	4.24.1.2		end apply <u>ing</u> inclusion crite opropriate for placement in	eria regarding which drugs <u>= and</u> the APDS and for which
				ıding when consultation is n	
		<u>4.24.1.3</u>	• .	ents are aware that consulta	•
	<u></u>	<u>4.24.1.4</u>	Describing ass and other per	signment of responsibilities	including those delivered via APDS and training of pharmacy personnel at location regarding maintenance
		<u>4.24.1.5</u>	Orienting pati medications a	ents on <u>the</u> use of APDS and are not available in the APDS	d notifying patients when expected i. The pharmacy must ensure the ne delivery of drugs and devices.
		<u>4.24.1.6</u>			s to patients expecting medications is disabled or malfunctions.
		Date o	f Last Policy Re	eview:	
□	demo	onstrating S. Attach a	g their informe	onsent form to the back of t	bed drug <u>s</u> and devices from the
<del>Yes No N/A</del>					
╚	ident	ified pati	·	d devices to the patient or tl	each patient and only release the ne patient's agent. [BPC
	4.2₹	<u>1</u> .4 The pl	narmacist has p	erformed all clinical service	es as part of the dispensing process. consultation. [BPC 4119.11(d)(4)]
	after	the phar	macist has revi		uthorization from the pharmacist the patient's profile for potentials 0.11(d)(5)]
<u>_</u>	devic phar	es dispen	nsed from the A a telecommuni	APDS. The consultation shall	t time on all prescribed drugs and be provided by a Board_licensed audio and video capabilities. [BPC
	_	_		inently post a notice that pr armacy [BPC 4119.11(d)(7)]	ovides the name, address and
□			rescription labe .5. [BPC 4119.1	= :	a APDS shall comply with BPC 4076
17	M-112	ያ (Rev. 1 <del>2</del>	/ <del>18</del> 2 <u>23)</u>	Page 15 of 45	PIC Initials

	14.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the
	pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]
	4.2 <del>8</del> 5 The federal warning label prohibiting transfer of controlled substances is on the
	prescription container. [21 CFR 290.5]
	prescription container. [21 crit 250.5]
Yes No N	/A
	4.2 <u>96</u> 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]
	When requested by the parenaser. [15 056 1475(b), 10 cm 1700:15, cen 1717]
	4. <del>30</del> 27 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
	4. <del>33</del> Patient package inserts are dispensed with all estrogen medications. [21 CFK 510.515]
	7.0.00=1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	4.3428 The pharmacy provides patients with Black Box Warning Information in conformance
	with 21 CFR 201.57(c).
	<b>,</b>
	J 4. <del>22</del> 29Medication guides are provided on required medications. [ <u></u> {21 CFR 208.1]}
	7
	4.30 The pharmacy uses the APDS to deliver prescription medications to patients as provided:
	[CCR 1713(d)]
	■ 4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion
	criteria for use of the APDS established by the pharmacy prior to the delivery of the
	prescription medication to the patient.
	4.30.2 The APDS has a means to identify each patient and only release the patient's
	prescription medications to the patient or patient's agent.
	·
	4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-
	person or via telephone, upon the request of a patient.
	4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has
	occurred shall be reviewed as part of the pharmacy's quality assurance program mandated
	by Business and Professions Code section 4125.
	CORRECTIVE A CTION OR A CTION RIAN AND COMPLETION RATE
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
V N	E. RECORD KEEPING REQUIREMENTS
Yes No N	
└── <del></del>	J-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)]

			!	n and disposition of dangerous
	4.3 <u>51</u> Any of the charge, or during whelectronic	records maintained ele the pharmacist on dut ich the licensed premis	ses are open for business, be a acquisition and disposition or c	. ,, ,-
	CORRECTI	VE ACTION OR ACTION	PLAN AND COMPLETION DAT	E
Yes No N/		LICIES AND PROCEDU	RES	
		•	ed and implemented written p he policies are reviewed annua	•
	<u> </u>	Maintaining the secur	rity of the APDS and dangerous	s drug <u>s</u> and devices within the
	<u>4.32.2</u>	appropriate for place	inclusion criteria regarding wh ment in the APDS and for whic	<u> </u>
	<u> </u>			a pharmacist is available for any a APDS.
	<u>4.32.4</u>	Describing assignmen	t of responsibilities and training the APDS at that location rega	ng of pharmacy personnel and
	<u>4.32.5</u>	Orienting patients on medications are not a	use of <u>the</u> APDS and notifying vailable in the APDS. The phar	macy must ensure the use of the
	<u>4.32.6</u>	Ensuring the delivery	ere with the delivery of drugs a of drugs and devices to patien the event <u>if</u> the APDS is disable	ts expecting medications
			r Review: and procedures for security me iversion. [BPC <u>4427.2(d)(3)</u> 410	
		pharmacy reports drug 6, 21 CFR 1301.76]	losses as required by law. [BP	C 4104, <u>4427.2(d)(4)</u> <del>4105.5(c)</del> ,
	17M-112 (	(Rev. 1 <del>≩</del> / <del>18</del> <u>2⊋3</u> )	Page 17 of 45	PIC Initials

	Last R	eported Drug Loss:
	CORRE	ECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
		ON 5: ADDS  APDS ADJACENT TO THE SECURED PHARMACY AREA OR  APDS LOCATED IN MEDICAL OFFICES (OR)
		APDS A LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS  AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE (OR)  APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.
		GENERAL REQUIREMENTS
es No N/A	5.1 Th	e pharmacy maintains the APDS policies and procedures for 3 years after the last date of r that APDS. [BPC 4427.6(I), CCR 1713(f)]
]	5.2 Th	e pharmacy developed and implemented, and reviewed annually the APDS policy and
	•	dures pertaining to the APDS, including: [BPC 4427.6(a)]
	•	Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
	•	Determining and applying inclusion criteria regarding which drugs and devices are
	•	appropriate for placement in the APDS and for which patients.  Ensuring patients are aware consultation with a pharmacist is available for any
		prescription medications, including those delivered via the APDS.
	•	Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding
		maintenance and filing procedures for the APDS.
	•	Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient
		use of the APDS does not interfere with delivery of drugs and devices.
	•	Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.
	5.2 Th	e pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR
	<u>1713(</u>	<u>d)]</u>
	<u> </u>	5.2.1 A pharmacist has determined that each patient using the APDS meets inclusion

Page 18 of 45

PIC Initials \_\_\_\_\_

		criteria for use of the APDS	S established by the pharmacy	prior to deliver of
		prescription medication to	the patient.	
	□ 5.2.2	The APDS has a means of i	dentifying each patient and or	nly release that patient's
		prescription medication to	the patient or patient's agent	<u>=</u>
	<u>□</u> <u>5.2.3</u>	The pharmacy provides an	immediate consultation with	a pharmacist, either in-
		<u>person or via telephone, u</u>	pon the request of a patient.	
	<u>□</u> <u>5.2.4</u>	Any incident involving the	APDS where a complaint, deli-	very error, or omission has
		occurred shall be reviewed	d as part of the pharmacy's qu	ality assurance program
		mandated by Business and	Professions Code section 412	<u>:5.</u>
es No N/A	1			
		rmacy does not have more t	than 15 APDS licenses for one	underlying operating
	•	•	7.6(k)] List of current APDS lice	, , , ,
	-		2	
	3		4	
	5		6	
	7		C	
	/		8	
	9		10	
	J		10	
	11.		12	
	13		14	<del></del>
	15		<del></del>	
	CORRECTIV	E ACTION OR ACTION PLAN	AND COMPLETION DATE	
		DOMESTIC CONTRACTOR		
3.PHAR 'es No N/A		PONSIBILITIES:		
		nacist licensed by the hoard	performs all clinical services co	onducted as nart of the
	•	•	mited to, drug utilization review	•
	[BPC 4427.6	- <del>-</del>		
	-			
	<b>17M-112</b> (R	Rev. 1 <del>2</del> / <del>18</del> <u>223</u> )	Page 19 of 45	PIC Initials

	5.5 Drugs are dispensed from th pharmacist has reviewed the precontraindications and adverse d	escription and the patient's prof	•
Yes No N/A	5.6 The pharmacist shall consult dispensed from the APDS. All property for the first time are accorpharmacist. The consultation shatelecommunication link that has	escribed drugs and devices dispendenced by a consultation conditional be provided by a Board license.	ensed to the patient from the ucted by a California licensed sed pharmacist via
<del>Yes No N/4</del>	$\Box$ 5.7.2 Access to ADDS/APDS	nces added to the ADDS/APDS a S is limited to authorized facility	re accounted for; personnel;
	substance is perform <u>5.7.4</u> Confirmed losses of c	•	<u>  Self-Assessment pursuant to</u>
	APDS. [BPC 4427.7(a)]  Date of Last Self-Assessment:  CORRECTIVE ACTION OR ACTION		=
Voc No N/0	C. DEVICE REQUIREMEN	NTS:	
¥es No N/A	5.9 The stocking of the APDS is positive internion pharmacist under the support of the facility pursuant to HSC 1250, who performed in compliance with H	ervision of a pharmacist, except nere the stocking and restocking	t for an APDS located in a health
	5.10 Access to the APDS is contr biosensor. [BPC 4427.4(e)(2)]	elled and tracked using an ident	tification or password system or
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 20 of 45	PIC Initials

	5.11 The ADDS makes a complet	e and accurate record of all tra	nsactions including all users
	accessing the system and all dru	gs added to, or removed from,	the system. [BPC 4427.4(e)(3)]
	5.12 Drugs and devices not immoderation are stored for no longer Upon retrieval of these drugs an any losses or overages. [BPC 442]	d devices from secured storage	om within the APDS location.
	5.13 Drugs stored in the APDS ar	e part of the inventory of the	operating pharmacy and drugs
	dispensed by the APDS shall be o	considered to have been disper	nsed by the pharmacy.
v 81 81/1	<del>[BPC 4427.4(d)]</del>		
Yes No N/A	5. <u>148</u> The APDS may only be use demonstrating their informed contact across at the consent for	onsent to receive prescribed dr	ug and devices from the APDS.
	5.459 The APDS has a means to i drugs and devices to the patient		•
	5. <u>1610</u> The APDS has a notice, praddress, and phone number of t	• •	S, which provides the name,
	5. <del>17</del> 11 Any incident involving the reviewed as part of the pharmac [BPC 4427.6(i)]	·	
	5. <u>1812</u> If the APDS is located and are regularly seen for purposes of dangerous drugs and dangerous	of diagnosis and treatment, the	e APDS is only used to dispense
	5. <del>19</del> 13 The labels on all drugs an with section 1707.5 of Title 16 or		DS comply with section 4076 and tions. [BPC 4427.6(h)]
	5. <del>20</del> 14 The federal warning laber prescription container. [21 CFR 2		olled substances is on the
	5.2415 Prescriptions are dispense of-opening tested container, or in when requested by the purchase	n a non-complying package on	• •
	5. <del>22</del> 16 Patient package inserts a	are dispensed with all estrogen	medications. [21 CFR 310.515]
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 21 of 45	PIC Initials

	5. <del>23</del> <u>17</u> The pl with 21 CFR 2		itients with Black Box Warnir	ng Information in conformance
	5. <del>24</del> <u>18</u> Medic	cation guides are pro	vided on required medicatio	ns. [21 CFR 208.1]
	CORRECTIVE	ACTION OR ACTION I	PLAN AND COMPLETION DAT	E
Yes No N/A	4	CORD KEEPING REQ	UIREMENTS	ing and quality assurance
	•	01 /	27.6 and those records shall	0 1 7
	•	•	rom the other pharmacy rec	•
		• • •	II maintain records of acquis OS separate from other phar	ition and disposition of macy records. [BPC 4119.11(a)(4)]
	charge, or the during which electronic cop	e pharmacist on duty the licensed premise	if the pharmacist-in-charge es are open for business, be a equisition and disposition or	ned so that the pharmacist-in- is not on duty, must, at all times able to produce a hardcopy and other drug or dispensing-related
	CORRECTIVE A	ACTION OR ACTION I	PLAN AND COMPLETION DAT	E
Yes No N/A	_	DLICIES AND PROCEE	DURES	
	respect to all		e policies are <u>maintained and</u>	policies and procedures with dare in procedure with
	<u>□</u> <u>5.21.1</u>	Maintaining the sec	curity of the APDS and dange	erous drug and devices within the
	<u> </u>	Determin <u>ing</u> -e and	apply <u>ing</u> inclusion criteria re placement in the APDS and	garding which drugs <u>and</u> ; devices for which patients.
		any prescription m	edication including those del	<del>-</del>
	□ 5.21.4	Describing assignm	ent of responsibilities and tra	aining of pharmacy personnel
	<b>17M-112</b> (Rev	/. 1 <del>2</del> / <del>18</del> <u>2<del>2</del>3</u> )	Page 22 of 45	PIC Initials

	and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.  □ 5.21.5 Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.  □ 5.21.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.
/ NI- NI//	Date of Last Policy Review:
es No N/A	5. <del>29</del> 22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)4105.5(c), CCR 1715.6, 21 CFR 1301.76]
	Last Reported Drug Loss:
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 — LONG-TERM-CARE  FACILITIES_THAT COMPLIES WITH HSC 1261.6  A. GENERAL REQUIREMENTS
	FACILITIES THAT COMPLIES WITH HSC 1261.6
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS
es No N/A	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]
∕es No N/A	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]
∕es No N/A	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]
∕es No N/A	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (e), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2) 1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]  6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and
∕es No N/A	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6(a)(3)]  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

Page 23 of 45

PIC Initials \_\_\_\_\_

	6.42 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]				
	CORRE	ECTIVE ACTION OR AC	CTION PLAN AND COMPLETION DA	TE	
Yes No N/A	В.	PHARMACIST RESP	ONSIBILITIES:		
	6. <u><del>5</del>3</u> Th pocket the sto	ts, cards, drawers, sir ocking system may be	DDS is performed by a pharmacist, on the property of use or seed one outside the facility and be detected: [BPC 4427.4(e)(1), HSC 1261.6(green)	single dose containers <del>-are used</del> , delivered to the facility if the	
		use or single dose c	ontainers is performed by a pharm	pockets, cards, drawers, or unit or nacist, or by an intern pharmacist of a pharmacist. [BPC 4427.4(e)(1),	
		6. <u>53</u> .2 The removable are transported bet container. [HSC 126	·=···	y in a secure tamper-evident	
	Ц	procedures to ensu	n conjunction with the pharmacy, let that the removable pockets, care ers are properly placed into the AD	ds, drawers, or unit of use or	
Yes No No	6. <u>64</u> In	<u>-</u>	cific access to the ADDS is limited this terminate of the contract of the cont	to facility and contract personnel	
	ADDS 1	for administration to	and approves all orders prior to a c a patient. The pharmacist reviews al contraindications and adverse d	the prescriber's orders and the	
			substance for a patient in a license facility is dispensed only after the		
		prescriber and only	pharmacist on a form developed by	prescription to writing in ink in the	
		☐ <u>6.6.1.1</u> The o	date the prescription was orally tra name of the person for whom the I		
	17M-1	. <b>12</b> (Rev. 1 <del>2</del> / <del>18</del> <u>2⊋3</u> )	Page 24 of 45	PIC Initials	

□ 6.6.1.3	The name and address of the licensed skilled nursing facility or licensed
	intermediate care facility in which the person is the patient.
□ 6.6.1.4	The name and quantity of the controlled substance prescribed.
□ <u>6.6.1.5</u>	The directions for use, and the name, address, category of the
	professional licensure, license number, and federal controlled substance
	registration number of the prescriber.
□ 6.6.1.6	The prescription is endorsed by the pharmacist with the pharmacy's
	name, license number, and address.
6.6.2 Prior to	o filling a prescription for a Schedule II controlled substance that has been
	y transmitted, the pharmacist has produced, signed, and dated a hard
	ption. The prescription must contain: [HSC 11167.5(a)]
	<del> </del>
□ 6.6.2.1	The date the prescription was electronically transmitted by the
	prescriber;
□ 6.6.2.2	The name of the person for whom the prescription was authorized;
<u> </u>	
<del></del>	intermediate care facility in which the person is the patient;
□ 6.6.2.4	The name and quantity of the controlled substance prescribed;
□ 6.6.2.5	The directions for use, and the name, address, category of the
<del></del>	professional licensure, license number, and federal controlled substance
	registration number of the prescriber.
□ 6.6.2.6	The prescription is endorsed by the pharmacist with the pharmacy's
	name, license number, and address.
□ 6.6.2.7	
	controlled substance for the licensed skilled nursing facility or licensed
	intermediate care facility.
	<del></del>
6.6.3 An orig	inal Schedule II prescription is written on a form that complies with Health
and Safety C	ode section 11162.1. [HSC 11164(a)]
6.6.4 An orig	inal Schedule II prescription is written with the "11159.2 exemption" for
the terminal	<u>ly ill. [HSC 11159.2]</u>
<u>6.6.5 In an e</u>	mergency where failure to issue the prescription may result in loss of life
or intense su	uffering, a Schedule II controlled substance may be dispensed from a
prescription	transmitted orally or electronically by a prescriber or written on a form
not as specif	ied in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]
<u>□</u> <u>6.6.5.1</u>	The order contains all information required by subdivision (a) of Section
	<u>11164.</u>

	<u>□</u> <u>6.6.5.2</u>	If the order is written by the prescriber, the prescription is in ink, signed,
		and dated by the prescriber.
	<u>□</u> 6.6.5.3	If the prescription is orally or electronically transmitted, it must be
		reduced to hard copy.
	□ 6.6.5.4	The prescriber provides a written prescription on a controlled substance
		form that meets the requirements of HSC 11162.1 by the seventh day
		following the transmission of the initial order.
	☐ <u>6.6.6 An elec</u>	ctronic prescription (e-script) for controlled substances that is received
	<u>from the pre</u>	scriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]
N/A		
	the ADDS is conducte inspection of the ADI	the drugs contained within the ADDS and the operation and maintenance of ed, on a monthly basis, by a pharmacist. The review includes a physical DS for cleanliness, and a review of all transaction records in order to verify buntability of the system. [HSC 1261.6(h)]
	Date of Last Review:	
	6. <u>98</u> The <u>p</u> ₽harmacis [CCR 1715.65(h)]	t-in-charge of the offsite ADDS has ensured the following:
	☐ <u>6.8.2</u> Access t ☐ <u>6.8.3</u> An ongo controll	rolled substances added to the ADDS are accounted for; o ADDS is limited to authorized facility personnel; sing evaluation of discrepancies or unusual access associated with ed substance is performed; and ed losses of controlled substances are reported to the Board.
		operating the ADDS has completed an <u>biennial</u> Self-Assessment pursuant luating the pharmacy's compliance with pharmacy law relating to the use $[427.7(a)]$
	Date of Last Self-Asse	essment:
	CORRECTIVE ACTION	OR ACTION PLAN AND COMPLETION DATE
	C. DEVICE REQU	IREMENTS:
N/A		
		and restocking of the ADDS is performed in compliance with section 1261.6 ety Code. [BPC 4427.4(e)(1), HSC 1261(c), (g)]

	6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS
	location are stored for no longer than 48 hours in a secured room within the ADDS location.
	Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect
_	any losses or overages. [BPC 4427.4(f)]
Yes No N/A	6. $\frac{13}{11}$ Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]
	$6.\underline{4412}$ 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)]
Voc No N/0	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)]:
	6.4513 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)]
	$6.\underline{14}$ Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]
	6.4715 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	•
	$6.\underline{4816}$ 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)]
	$6.\underline{4917}$ 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. <del>20</del> 18 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6(f)(3)]

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<del>2</del>3) Page 27 of 45

PIC Initials \_\_\_\_\_

	6.21 Access to the ADDS is controlled an	d tracked using an identification	<del>on or password system or</del>	
	biosensor. [BPC 4427.4(e)(2), HSC 1261.	<del>6(f)(4)]</del>	. ,	
	6.22 The ADDS makes a complete and a	curate record of all transactio	ns that includes all users	
	accessing the system and all drugs adde	d to, or removed from, the sys	tem. [BPC 4427.4(e)(3),	
	HSC 1261.6(f)(5)]			
Yes No N/A	<u> </u>			
	6.2319 After the pharmacist reviews the ADDS is limited only to drugs ordered by that are specific to the patient. [HSC 12]	y the prescriber and reviewed	•	
	6.2420 When the prescriber's order requestream personnel only have access to the drug [HSC 1261.6 (f)(6)]	<del>-</del>	<u> </u>	
	6.2521 If the ADDS allows licensed personation specific in its their design, the AI place to ensure that the drugs delivered (HSC 1261.6(f)(7)).	DDS has electronic and mechai	nical safeguards in	
	Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]  CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE			
Yes No N/#	established in pharmacy law and regulat	ordkeeping and quality assura ion, and maintains those reco	rds within the licensed	
	pharmacy holding the ADDS license and	separate from the other phari	<del>nacy records.</del>	
	[BPC 4427.7(b)]			
Yes No N/A	6. 全型 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)]			
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> <u>223</u> )	Page 28 of 45	PIC Initials	

	6.23 Records of inspections completed by the pharmacist are kept for at least three years.
	[HSC 1261.6(b), 22 CCR 70263(f)(3)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/A	E. POLICIES AND PROCEDURES
	6.2824 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)]
	6.2925 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]
	6.3026 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)]
	6.3127 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)] 6.3328 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
	<b>4190 17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <del>2</del> 3)  Page 29 of 45  PIC Initials

### **A. GENERAL REQUIREMENTS**

Yes No N//	4 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
	<del>1204.1. [BPC 4427.3(b)(3)]</del>
	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 ADD
	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.
	<del>[CCR 1715.65(a)]</del>
	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:
	<ul> <li>A physical count (not estimate) of all quantities of all federal Schedule II controlled substances.</li> </ul>
	A review of all acquisition and disposition records of federal Schedule II controlled
	substances since that last inventory reconciliation report:
	Date of last inventory
	4784 443 (Pov. 42/40222) Pogo 20 of 45 PiC initials

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

Yes No I	<del>1/4</del>
	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, furthe
	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 an
	sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic fo
	<del>3 years. [CCR 1715.65(e)]</del>
	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.
	<del>[BPC 4427.6(i)]</del>
	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]
	<u> </u>
	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
	<del>21 CFR 201.57(c).</del>
ШШ	→ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]
	7.740 to the ABBC to select and a select and a select and a discount of a select and a select an
——	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:
	Elst of Garrent in Bonochiscor
	<del>1. 2 </del>
	<del></del>

	<del>੬</del>	k
	5.	6.
	_	•
	<del>/</del>	<del>8</del>
	9.	10.
	44	4.2
	<del>11.</del>	±4•
	<del>13.</del>	14.
	4-	
	<del>15.</del>	
	CORRECTIVE ACTION OR ACTION BLAN AND COMPI	ETION DATE
	CONNECTIVE ACTION ON ACTION FEATS AND CONTR	ELHON DATE
<del>(es No N//</del>	B:—PHARMACIST RESPONSIBILITY  A  7.20 The pharmacist performs the stocking of the Al	<del>DDS. [BPC 4186(c)]</del>
	7.21 Drugs are removed from the ADDS system only	upon the authorization of the pharmacist
	after the pharmacist has reviewed the prescription	
	•	·
	contraindications and adverse drug reactions. [BPC	<del>-4186(0)]</del>
	7.22 The pharmacist shall conduct a review on a mo	nthly basis including a physical inspection of
	the drugs in the ADDS for cleanliness and a review	
	•	,
	the security and accountability of the ADDS. [BPC 4	<del>186(d)]</del>
	Date of Last Review:	
	7.23 The pharmacist licensed by the board performs	all clinical services conducted as part of the
	dispensing process, including, but not limited to, dr	us utilization review and consultation.
	[BPC 4427.6(d)]	0
	<del>[DI C 1127.0(u)]</del>	
<del>'es No N//</del>	<b>A</b>	
	7.24 Drugs are dispensed from the APDS after the p	harmacist has reviewed the prescription and
	the patient's profile for potential contraindications	·
	тие рамент в речине пот роченила сопитантансации	and adverse drug reactions, [br & 4427.0(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)]
	7.20 The pharmaciat apparation the ADDC shall be leasted in Colifornia [DDC 410C/f)]
	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/	G. 10101071110111001201111
	7.32 The pharmacy has developed and implemented, and reviewed annually, written policies
	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)]
	and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> </ul>
	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
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC-4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>Describing assignments of responsibilities to, and training of, pharmacy personnel, and other</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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.</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>Describing assignments of responsibilities to, and training of, pharmacy personnel, and othe 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.</li> <li>Orienting participating patients on the use of the APDS, notifying patient when expected</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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.</li> <li>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</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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.</li> <li>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.</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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.</li> <li>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.</li> <li>Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.</li> </ul>
	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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.</li> <li>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 interest of drugs and devices to patients expecting to receive them from the APDS</li> </ul>
<del>Yes No N/</del>	<ul> <li>and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]</li> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> <li>Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.</li> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> <li>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.</li> <li>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.</li> <li>Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.</li> </ul>

Page 33 of 45

PIC Initials \_\_\_\_\_

**17M-112** (Rev. 1<del>2</del>/<del>18</del><u>22</u>3)

	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(I)]
	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	<u>87</u> : ADDS OPERATED BY A CORRECTIONAL CLINIC
Yes No N/A	A. GENERAL REQUIREMENTS
	<u>7</u> <b>8</b> .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)]
	<u>7</u> 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 Conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. $\frac{1}{2}$ [BPC 4187(a)].
Yes No N/A	<ul> <li><u>7</u>8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a), 4187.2]</li> <li>The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.</li> <li>An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2]</li> </ul>

Page 34 of 45

PIC Initials \_\_\_\_\_

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>2</u>3)

	<u>78</u> .4 The dispensing or administering of a chart order, as defined in section 4019 2 of the Business and Professions Code, within the statewide Inmate Medical Se Health Care Services Health Care Depart	), a valid prescription consisten or pursuant to an approved pr rvices Policies and Procedures.	t with chapter 9 division otocol as identified - <u>California Correctional</u>
Yes No N/A	<u>7</u> 8.5 Medications dispensed to patients		
	the labeling requirements of section 407 division 2 of the Business and Profession		rements of chapter 9
	78.6 The correctional clinic keeps record administered, transferred, and dispense maintained for a minimum of three year [BPC 4187.1(c)]	d. The records must be readily	available and
	78.7 The correctional clinic has obtained	l a license from the board. [BPC	C 4187.1(d)(1)]
	<u>7</u> 8.8 A separate license was obtained for located and is not to be transferrable. [E		on where an APDS is
	<u>7</u> 8.9 The correctional clinic's location an and building within the correctional inst	·	orrectional institution
	<u>7</u> 8.10 The correctional clinic will notify t address on a form furnished by the boar	-	ange in the clinic's
	8.11 The ADDS is secured from access an [BPC 4427.2(d)(2)]	d removal by unauthorized ind	<del>lividuals.</del>
	CORRECTIVE ACTION OR ACTION PLAN	AND COMPLETION DATE	
	B. POLICIES AND PROCEDURES		
Yes No N/A	N <u>7</u> 8.1 <u>21</u> The policies and procedures to ir the correctional clinic was developed an and Therapeutics Committee referenced	d approved by the statewide C	Correctional Pharmacy
	78.132 Prior to the issuance of the correct of the policies and procedures was signed		_
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 35 of 45	PIC Initials

Vac Na Ni	and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]
Yes No N/	$\frac{\Delta}{28}$ .143 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]
	78.154 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the statewide Inmate Medical Services California Correctional Health Care Services Policies and Procedures Health Care Department Operations Manual in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]
	$\underline{78}.165$ The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]
	78.176 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2, 4187.3]
	<u>78</u> .187 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services California Correctional Health Care Services Health Care Department Operations Manual Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]
	<u>78</u> .198 All policies and procedures are maintained either in an electronic form or paper form at the location where the <del>automated drug system</del> <u>ADDS</u> is being used. [BPC 4187.5(a)] CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/	C. PHARMACIST RESPONSIBILITIES
	78.2919 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

Page 36 of 45

PIC Initials \_\_\_\_\_

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>2</u>3</del>)

	78.2120 Drugs removed from the auto-	<del>mated drug system</del> AD	DS <del>is-</del> are removed upon
	authorization by a pharmacist after th	• • • <u> </u>	<del></del> •
	patient profile for potential contraindi	ications and adverse dr	ug reactions. <del>If the correctional</del>
	<del>pharmacy is closed,</del> Where administra	<b>*</b>	
	<u>reviewed the prescription</u> and if, <u>in</u> the	•	
	may cause patient harm, the medicati	•	
	system-ADDS and administered or furn	•	
	prescriber. Where the drug is otherwis	•	•
	administered or furnished to the patie the statewide Inmate Medical Services		•
	Care Services Health Care Department		
	an automated drug delivery ADDS sys		
	pharmacy when it reopens. [BPC 4187		a provided to the correctional
Yes No N/	• • •	.5(8)]	
		monthly basis by a pha	rmacist and shall include a physical
	inspection of the drugs in the automat	ted drug delivery system	<del>m-<u>ADDS</u>, an inspection of the</del>
	automated drug delivery system ADDS	$\underline{\underline{8}}$ machine for cleanline	ss, and a review of all transaction
	records in order to verify the security	and accountability of tl	ne system. [BPC 4187.5(e)]
	Date of Last Review:		
	Date of Last Neview.		<del></del>
	CORRECTIVE ACTION OR ACTION PLAN	I AND COMPLETION DA	\TF
			··· -
			-
			_
	D. DEVICE REQUIREMENT		
Yes No N/			
	78.2322 Drugs removed from the ADDS		
	licensed pursuant to division 2 of the I	Business and Profession	is code who is lawfully authorized
	to perform the task. [BPC 4187.5(c)]		
	78.2423 The review of the drugs contain	ined within, and the on	peration and maintenance of the
	ADDS shall be the responsibility of the	•	
	,		
	78.2524 The ADDS is operated by a lice	ensed correctional phar	macy. Any drugs within the ADDS
	are considered owned by the licensed		
	ADDS. [BPC 4187.5(f)]		
	78.2625 Drugs from the ADDS in the co		
	stock the ADDS, or by a person lawfull	y autnorized to admini	ster or dispense the drugs. [BPC
	4187.5(g)]		
	<b>17M-112</b> (Rev. 1 <del>≩/<u>18</u>2<u>≥</u>3</del> )	Page 37 of 45	PIC Initials

	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
/A	E. RECORD KEEPING REQUIREMENTS
_	78.2726 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is are preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	Please Note: Hospital pharmacies and drug rooms must also complete Section 6 for ADDS used for administration. This section addresses additional requirements for hospital
A	pharmacies and drug rooms operating an ADDS uses for dispensing.
2	pharmacies and drug rooms operating an ADDS uses for dispensing.  A. GENERAL REQUIREMENTS

					dispenses <u>a dangerous drug,</u> gency room patient, the following
			apply [BPC 4068(a)]:	<u></u>	geney room patients the rone ming
		<u>8.2.1</u>	when t The hospital pharr hospital.	nacy is closed and there	e is no pharmacist available in the
			The drugs <del>is </del> are acquired		
		<u>8.2.3</u>	The dispensing informatic pharmacy reopens.	on is recorded and provi	ded to the pharmacy when the
		<u>8.2.4</u>	•	tains the dispensing info	ormation <u>and, if the drug is a</u>
					substance, reports the dispensing nt to Section 11165 of the Health
		<u>8.2.5</u>	drug regimen be immedia	tely commenced or con a pharmacy located outs	t of the patient that a particular tinued, and the prescriber side the hospital is not available
		<u>8.2.6</u>	The quantity dispensed is uninterrupted therapy wh	limited to the amount nen pharmacy services o	
		<u>8.2.7</u>		at the label on the drug	contains all the information
Yes No N/A	8.3	•			Board to operate the AUDS that is
		7.2(i)]	<u>aministration and dispensi</u>	ng which includes the ac	ddress of the AUDS location. [BPC
<del>Yes No N//</del>	_		prescriber ensures the labo CCR 1707.5 <u>.</u>	el on the drug contains a	all the information required by BPC
			federal warning label <del>s</del> prol on container. [21 CFR 290.5		rolled substances is on the
	ease	== e-of-op		in a non-complying pac	resistant container, or senior-adult kage only pursuant to the request 5, CCR 1717]
	_		hospital pharmacy or drug ntrolled substance to the D	•	nsing information of a Schedule II, to HSC 11165 as soon as
	17N	<b>1-112</b> (	Rev. 1 <del>2</del> / <del>18</del> <u>223)</u>	Page 39 of 45	PIC Initials

	reasonably possible, but not mo dispensed. [BPC 4068(a)(4), HSC	•	ate a controlled substance is
Yes No N/A	<del>9.7</del> <u>8.8</u> Patient package inserts are	e dispensed with all estrogen r	medications. [21 CFR 310.515]
	9.88.9 The hospital has written p information regarding each drug from a drug room, including the warnings, and the importance of	given at the time of discharge use and storage of each drug,	e or dispensed from a prescriber the precautions and relevant
	9.9 The operating pharmacy has used for administration and disp		•
Yes No N//	8.10 Medication guides are provi	ded on required medications.	[21 CFR 208.1]
	8.11 Black box warning informati	on is in conformance with 21 (	CFR 201.57(c).
		sing the drug prominently disp tion mechanism attached to th	plays on the label or container, by ne container, a notice that states,
	CORRECTIVE ACTION OR ACTION	I PLAN AND COMPLETION DAT	E
	SECTION 9 – AUDS THROUGH A AUTHORITY TO PROVIDE PHARI DETENTION FACILITY, OR OTHER WITH THE FACILITY UNDER THE	MACEUTICAL SERVICES (OR) A R CORRECTIONAL FACILITY WI	UDS THROUGH A JAIL, YOUTH HERE DRUGS ARE ADMINISTERED
	A. GENERAL REQUIREMENT	<u>rs</u>	
Yes No N/E	9.1 Review of the drugs contained done in accordance with law and the review on a monthly basis, we	d is the responsibility of the phylich includes a physical inspe- liness, and a review of all trans	armacy. A pharmacist conducts ction of the drugs in the ADDS, an saction records in order to verify
	17M-112 (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 40 of 45	PIC Initials

	COF	RRECTI	VE ACTION OR ACTION PLAN AND COMPLETION DATE
		В. <u>Р</u>	IARMACIST RESPONSIBILITIES:
Yes No N/A			
	poc by t	kets, c the Uni	ocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable ards, drawers, similar technology, or unit of use or single dose containers, as defined ted States Pharmacopoeia, the stocking system may be done outside of the facility livered to the facility, if all the following conditions are met: [BPC 4427.65(c)(6)]
		9.2.1	The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
		9.2.2	The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
		9.2.3	The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS.
			armacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures the [CCR 1715.65(h)]
		9.3.1	All controlled substances added to an ADDS are accounted for.
			Access to the ADDS is limited to authorized facility personnel.  An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.
		<u>9.3.4</u>	Confirmed losses of controlled substances are reported to the board.
	<u>COF</u>	RRECTI'	VE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/A		C. <u>DE</u>	VICE REQUIREMENTS:

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>2</u>3)

Page 41 of 45

PIC Initials \_\_\_\_\_

	9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel
<u> </u>	authorized by law to administer drugs. [BPC 4427.65(c)(2)]
	<u> </u>
	When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed
	from the ADDS are limited to the following [BPC 4427.65(c)(4)]:
Voc No N//	
Yes No N/A	<u>9.5 A new drug order given by a prescriber for a patient of the facility for administration prior to</u>
	the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are
	retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the
	prescriber's order and the patient's profile for potential contraindications and adverse drug
	<u>reactions. [BPC 4427.65(c)(4)(A)]</u>
	9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization
	and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC
	4427.65(c)(4)(B)]
	9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee
	of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the
	ADDS pursuant to the order of the prescriber for emergency or immediate administration to
	the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the
	pharmacist. [BPC 4427.65(c)(4)(C)]
	When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:
	subject to the following requirements [BFC 4427.05[c](3)].
	9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled
	units of administration containers or packages. [BPC 4427.65(c)(5)(A)]
	9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the
	ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the
	patient's profile for potential contraindications and adverse drug reactions. [BPC
	<u>4427.65(c)(5)(B)]</u>
	9.10 The pharmacy providing services to the facility controls the access to the drugs stored in
	the ADDS. [BPC 4427.65(c)(5)(C)]
	9.11 After the pharmacist reviews the prescriber's order, access by licensed personnel to
	the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist
	and that are specific to the patient. When the prescriber's order requires a dosage variation of
	the same drug, licensed personnel has access to the drug ordered for that scheduled time of
	administration. [BPC 4427.65(c)(5)(F)]

	9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not
	patient specific in their design, shall be allowed if the ADDS has electronic and mechanical
	safeguards in place to ensure the drugs delivered to the patient are specific to the patient.
	[BPC 4427.65(c)(5)(G)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/A	D. <u>RECORD KEEPING REQUIREMENTS</u>
	9.13 Transaction information shall be made readily available in a written format for review and
	inspection by individuals authorized by law and are maintained in the facility for a minimum of
	three years. [BPC 4427.65(c)(1)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	CONNECTIVE METION ON METION PAIN TENT CONTINUE C
Yes No N/A	E. <u>POLICIES AND PROCEDURES</u>
	9.14 The pharmacy operating the AUDS shall develop and implement, and review annually, the
	written policies and procedures pertaining to the ADDS. [BPC 4427.65(b)]
	0.15 The facility and the pharmacy has developed and implemented written policies and
<u> </u>	9.15 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and
	maintenance of the quality, potency, and purity of stored drugs. The policies and procedures
	define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)
	0.4C All religions and reproduces are resintained at the alternative that ADDC and the
<u> </u>	9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]
	Todation where the his is semigrased. [STO TIZ7.5(c)(SA)5)
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

#### CERTIFICATION ACKNOWLEDGMENT

_		
PHARMACIST-IN-CHARGE CER	TIFICATION:	
responses are subject to verific	t of this automated drug deliciency identified herein will cation by the Board of Pharnate of California that the info	_ hereby certify that I have ivery system of which I am the be corrected. I understand that all nacy. I further state under penalty ormation that I have provided in
Signature (Pharmacist-in-Cha	Date	··································
ACKNOWLEDGMENT BY OWN OPERATING THE OF ADDS:  I, (please print)		HOSPITAL ADMINISTRATOR  ert name and title], hereby certify
without any limitations to prov the Hospital Administrator Ope acknowledge that all facts and	vide this certification, that I de erating the ADDS and that I h Information stated herein is	California that I have full authority, am the Owner of the Pharmacy or have reviewed this form, and strue, correct and complete. read derstand that failure to correct any
deficiency identified in this self drug delivery system's license i		the revocation of the automated e Board of Pharmacy.
Signature	Date	

#### **CERTIFICATION OF COMPLETED ACTION PLAN**

PHARMACIST-IN-CHARGE CERT	IFICATION:	
corrected the deficiencies ident system of which I am the pharn verification by the Board of Pha	hereby certify that I have ified in the self-assessment of this automated drug deliver nacist-in-charge. I understand that all responses are subject rmacy. I further state under penalty of perjury of the laws information that I have provided in this self- assessment for	t to of
Signature(Pharmacist-in-Cha	rge)	
ACKNOWLEDGMENT BY <i>OF TH</i> <del>OE</del> ADDS:	E PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING	THE
without any limitations to provi the Hospital Administrator Ope acknowledge that all facts and	[insert name and title], hereby certife the laws of the State of California that I have full authorised this certification, that I am the Owner of the Pharmacy of the ADDS and that I have reviewed this form, and information stated herein is true, correct and complete.	ity, or <del>id</del>
deficiency identified in this self	assessment could result in the revocation of the automate sued by the California State Board of Pharmacy.	•
Signature	Date	

# **Attachment 2**



#### 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





#### Proposed Regulation to Amend Title 16 CCR Section 1715.1, ADDS Self-Assessment

Summarized 15-day Comments Regarding the ADDS Self-Assessment with Board Staff Recommendations:

## <u>Written Comments from Greg Doe, Pharm.D., California Correctional Health Care Services (CCHCS)</u>

Comment 1: CCHCS indicates that they operate approximately 39 licensed Correctional Pharmacies, 320 licensed Correctional Clinics, and 480 Automated Drug Dispensing Systems (ADDS) across 33 Institutions. This means that CCHCS Correctional Pharmacies average 13 automated drug dispensing systems per pharmacy. Commenter indicates that all 480 ADDS are made by the same manufacturer, controlled by the same software system on a single server, and function under the same set of policies and procedures. Currently, CCHCS licensed correctional pharmacies are completing a separate paper ADDS self-assessment for each of the ADDS which therefore requires duplication of the same information across many individual paper self-assessments.

CCHCS is requesting that the following subsection be added to the regulation text at section 1715.1:

- (g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliance with federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:
  - (1) The mechanical devices used as part of the automated drug delivery system tostore, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;
  - (2) The same policies and procedures required by Section 4427.2 of BPC are used:
  - (3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment; and
  - (4) Each single consolidated self-assessment is limited to ADDS devices which are located at a single institution and under a single Chief Executive Officer.

**Response to Comment 1**: Board staff have reviewed this comment and recommend that the text be amended to include some of the language provided by CCHCS. Specifically, board staff recommend that the following language be added as a new subsection (g):

- (g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliance with federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:
- (1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;
- (2) The same policies and procedures required by Section 4427.2 of BPC are used; and
- (3) All mechanical devices for which the single consolidated selfassessment applies shall be listed with license number and expiration date as part of the self-assessment.

Board staff further recommend that language being added in subsection (f)(3) that would include a listing of all of the unlicensed ADDS covered under the single self-assessment.

**Comment 2**: The commenter recommended that the self-assessment form its-self be amended to add a section to allow for Correctional pharmacies to list all of the ADDS device license numbers and expiration dates. Sample language was provided:

This is a consolidated Automated drug delivery system self-assessment for AUDS operated by a licensed operated by a licensed correctional pharmacy inclusive of the following ADDS Licenses [CCR 1751.1(g)]:

ADDS License #:	_ ADDS Expiration Date:
ADDS License #:	_ ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:

**Response to Comment 2**: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that this comment is outside the scope of the 15-day comment period. Additionally, Board staff note that if an individual self-assessment form is being completed for more than one ADDS license, the licensee can attach a separate page to the self-assessment form that lists all of the ADDS license numbers and expiration dates in lieu of documenting all of the licenses directly on the form.

## <u>Written Comments from Loriann DeMartini, California Society of Health-System Pharmacists, Pharm.D.</u>

The commenter resubmitted their comments previously submitted during the 45-day comment period. Commenter restated their concern about the combination of statutes and the deviation in the language from the Hospital self-assessment form.

For ease of review, the summarized comments from the 45-day comment period are provided below with staff responses.

**Comment 3**: The commenter recommended that section 1.3 be amended to remove "by a physician in a drug room or hospital emergency room when the pharmacy is closed" as BPC 4056 and 4068 do not mention AUDS devices and were not intended to be included with AUDS devices.

**Response to Comment 3**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. Staff, however, did suggest inclusion of an additional reference of BPC 4427.65 to section 1.3 on the self-assessment form. Inclusion of the additional reference is a non-substantive change and will provide additional clarity to the regulated public.

**Comment 4**: The commenter recommended that section 2.3 be amended to specify skilled nursing facility, intermediate care facility, and nursing facility as complying with HSC 1261.6 to avoid confusion. Further, commenter recommends breaking down the specific questions by facility type.

**Response to Comment 4**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, the language on the form mirrors the statute. Mirroring the statute ensures consistency of information and provides the specific legal sections that allows the pharmacist-in-charge to reference if clarification is needed.

**Comment 5**: The commenter recommended that section 2.8 be amended to separate the requirements of BPC 4427.2(i) and 4056 as they are two separate statutes. Additionally, commenter recommended removal of the term "drug room" as it is not identified in the statute. Finally, the commenter recommended that the language be shortenedd for ease of understanding by the PIC.

**Response to Comment 5**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, statutes are not taken separately, but

collectively establish the requirements. Additionally, Board staff noted that the term "drug room" is utilized by the Board within the form as a licensed hospital that contains 100 beds or fewer.

**Comment 6**: The commenter recommended that section 2.9 be amended to separate the requirements of BPC 4427.2(i) and 4068 as they are two separate statutes.

**Response to Comment 6**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, statutes are not taken separately, but collectively establish the requirements.

**Comment 7**: The commenter recommended that section 2.10 be amended to include a list of facility types for the PIC to select from instead of utilizing an openended question that is subject to the PICs interpretation.

**Response to Comment 7**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, the language on the form mirrors the statute, which ensures consistency of information. The form includes related references for the PIC to consult should they need additional clarification on which types of facilities are eligible.

**Comment 8**: The commenter recommended that all requirements listed within Section 6 and the general requirements be amended to specify skilled nursing facility, intermediate care facility, and nursing facility as complying with 1261.6 to avoid confusion and to clarify that it doesn't apply to general acute care hospitals and acute care psychiatric facilities.

**Response to Comment 8**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, the language on the form mirrors the statute. Mirroring the statute ensures consistency of information and provides the specific legal sections that the pharmacist-in-charge can refer to if clarification is needed. Board staff also notes that provisions apply to all health facilities licensed pursuant to HSC 1250, not those only referenced in HSC 1261.6.

**Comment 9**: The commenter recommended that the "Note" under Section 8 be removed because Section 6 does not apply to hospitals or drug rooms.

**Response to Comment 9**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, section 6 provides the requirements for ADDS

used for administration, as indicated on the form. Where a hospital ER is using an ADDS for dispensing as allowed under 4068 and a drug room as allowed under 4056, the provisions included in Section 8 are applicable.

**Comment 10**: The commenter recommended that section 2.8 be amended to separate the requirements of BPC 4427.2(i) and 4056 as they are two separate statutes. Additionally, commenter recommended removal of the term "drug room" as it is not identified in the statute. Finally, the commenter recommended that the language be shorted for ease of understanding by the PIC.

**Response to Comment 10**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, statutes are not taken separately, but collectively establish the requirements. Additionally, Board staff note to the term "drug room" is utilized by the Board within the form as a licensed hospital that contains 100 beds or fewer.

**Comment 11**: The commenter recommended that section 8.2 be amended to separate the requirements of BPC 4427.2(i) and 4068 as they are two separate statutes. Additionally, the commenter states the language within the section deviates significantly from the form 17M-14 – Hospital Pharmacy Self-Assessment.

**Response to Comment 11**: Board staff have reviewed this comment a second time and do not recommend the change offered by the commenter. As referenced during the 45-day comment period, statutes are not taken separately, but collectively establish the requirements.

**Comment 12**: The commenter recommended that section 1751.1(c)(6) be amended to change the term "owner" to "site owner or administrator" as the use of the term "owner" requires a corporate officer or Board member to sign, which is problematic for large corporations.

**Response to Comment 12**: Board staff have reviewed this comment a second and do not recommend additional changes. The language on the form was amended prior to the 15-day comment period. Therefore, additional changes are not needed.

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

**Comment 13**: The commenter disagrees with the requirement for hospitals to complete the ADDS self-assessment form for unlicensed AUDS devices. The commenter states that the requirement for the completion of the ADDS self-assessment is specific to a "pharmacy holding an ADDS license" per BPC 4427.7(a) and BPC 4427.2(i) exempts these devices from licensure. The commenter does not

agree that section BPC 44727.2(i) requires compliance with the self-assessment requirement and provided a possible scenario as an example. Commenter recommends that 1751.1(f) be amended to read as follows (added language underlined):

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

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

**Response to Comment 13**: Board staff have reviewed this comment a second time and do not recommend any changes to the text based thereon. While BPC 4427.2(i) exempts an AUDS devices in a licensed hospital under specific circumstances, the statute also states that the AUDS shall comply with all other requirements for the ADDS within Article 25, which includes the requirement for the completion of the self-assessment. As mentioned by the commenter, the Board has had numerous policy discussions and reviewed this comment several times. Additionally, assigned counsels have repeatedly confirmed all legal obligations, including the completion of the ADDS self-assessment, equally apply to an unlicensed ADDS.

# **Attachment 3**

### Title 16. Board of Pharmacy Modified Regulation Text

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and <u>underline</u> for added language.

January 2023 changes are shown by *italicized double strikethrough* for deleted language and *italicized wavy underline* for added language.

April 2023 changes are show by <u>double wavy underline</u> for added language. [Changes are limited to Subdivisions (f) and (g)].

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

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

- (a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code (BPC) shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  - (1) A new automated drug delivery system license has been issued.
  - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.
  - (3) There is a change in the licensed location of an automated drug delivery system to a new address.
- (c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18223) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  - (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    - (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    - (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
    - (C) DEA registration number, expiration date, and date of most recent DEA inventory;
    - (D) Hours of operation of the pharmacy; and
    - (E) ADDS license number, address, and hours of operation.
  - (2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-

- assessment, in compliance with laws and regulations that apply to that pharmacy setting.
- (3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
- (4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
- (5) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has they have completed the self-assessment of the automated drug delivery system of which he or she is they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
- (6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she they have has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing drug delivery system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.
- (d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
- (e) Any identified areas of noncompliance shall be corrected as specified in the assessment.
- (f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:
  - (1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and
  - (2) The same policies and procedures required by Section 4427.2 of BPC are used.
  - (3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.
- (g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliance with federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional

#### pharmacy under the following conditions:

- (1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;
- (2) The same policies and procedures required by Section 4427.2 of BPC are used; and
- (3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.

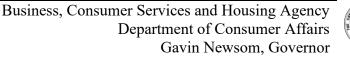
Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 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





**LEGEND:** Proposed changes made to the current regulation language are shown by <del>double strikethrough</del> for deleted language and <u>double underline</u> for added language.

2023 changes are shown by *italicized double strikethrough* for deleted language and *italicized wavy* underline for added language.

April 2023 changes are show by <u>double wavy underline</u> for added language. [Changes are limited to Note at top of page 10].

#### **AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT**

Business and Professions Code (BPC) section 4427.7(a) requires that the pharmacy holding an automated drug delivery system (ADDS) license complete an annual a self-assessment, performed pursuant to section 1715.1 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed before July 1 of every odd-numbered year by the pharmacist-in-charge of each pharmacy under BPC sections 4029 (Hospital Pharmacy) or section-4037 (Pharmacy). The pharmacist-in-charge (PIC) must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, er-(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 <u>Division 2</u>, Chapter 9<del>, Division 2</del>; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

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

Note: For a hospital pharmacy operating an ADDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the ADDS. The hospital pharmacy is required to comply with all other requirements including completing the ADDS Self-Assessment pursuant to BPC 4427.7(a). The PIC may complete a single self-assessment if the mechanical devices used are the same and the same policies are procedures are used. (CCR 1715.1(g))

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

		Zip Code:				
Phone:				Fax numb	er:	
Web						
DEA Inventory Date:						
			DEA Expiration Date:			
			Last 😝 <u>CS</u> Inventory Reconciliation Date (CCR 1715.65(c)):			
	macy Hours: N					Sunday
			RPH# ADDS Expiration Date:			
	S License #:			<del></del>		e:
	S Address:		Zip Code:			
City:						
				Saturday nt than the phar		Sunday
	ricase expiaii	ii tile ADD3 lit	buis are unitere	it tilali tile pilal	nacy.	
	Reason for co	npleting self-as	ssessment:			
	□ Performing	self-assessmer	nt before July 1	of every odd-nur	nbered ve	ar. [BPC 4427.7, CCR
	1715.1(a)]	Jen assessiner	THE DETOTE SUTY I	or every odd man	indered ye	<u> </u>
		a solf assassm	ant within 20 d	ave whom a now	ADDC licon	oca was issued IDDC
	-			<u>ays when a new .</u>	ADDS licer	ise was issued. [BPC
		R 1715.1(b)(1)]	•			
	-			<u>ays when there v</u>	<u>vas a chan</u>	<u>ge in PIC. [BPC</u>
	11277 CC	R 1715.1(b)(2)]				
	4427.7, CC	<u>(1/13.1(D)(2))</u>				
			nent within 30 d	ays when there v	vas a chan	ge in the licensed
	☐ Completing	a self-assessm		ays when there v		
	☐ Completing	a self-assessm				
	☐ Completing location of	a self-assessm an ADDS to a n	new address. [BI	C 4427.7, CCR 1		
	☐ Completing location of	a self-assessm an ADDS to a n		C 4427.7, CCR 1		
	Completing location of	a self-assessm an ADDS to a n	new address. [BF	ONS 1, 2 AND 3		
	Completing location of FOR ALL TYPE  SECTION 1: D	a self-assessman ADDS to a n  OF ADDS: CO	new address. [BF  OMPLETE SECTION  PE OF ADDS DE	PC 4427.7, CCR 1	715.1(b)(3	)]
	□ Completing location of  FOR ALL TYPE  SECTION 1: D  An ADDS – "A	a self-assessm an ADDS to a n OF ADDS: CO EFINITIONS/TYI utomated drug	DMPLETE SECTION  PE OF ADDS DE GOIL SECTION OF SECTION	PC 4427.7, CCR 1 PNS 1, 2 AND 3 VICE USED n," a mechanical	7 <u>15.1(b)(3</u> system th	<u>)]</u> at performs operatio
	Completing location of  FOR ALL TYPE  SECTION 1: D  An ADDS – "A  or activities of	a self-assessm an ADDS to a n OF ADDS: CO EFINITIONS/TY utomated drug her than compo	MPLETE SECTION  PE OF ADDS DE delivery syster ounding or adm	ONS 1, 2 AND 3  VICE USED  n," a mechanical inistration, relati	system the	at performs operation
	□ Completing location of Section 1: D An ADDS – "A or activities of distribution of	a self-assessman ADDS to a note of ADDS: CO  EFINITIONS/TYPE  Itomated drug  ther than compositions. An ADD  drugs. An ADD	PE OF ADDS DE delivery system ounding or admos, shall collect,	VICE USED  n," a mechanical inistration, relaticontrol, and mai	715.1(b)(3 system the ve to stora ntain all tr	at performs operation age, dispensing, or ansaction information
	□ Completing location of  FOR ALL TYPE  SECTION 1: D  An ADDS – "A  or activities of distribution of to accurately the section of the sectio	a self-assessman ADDS to a note of ADDS: CO  EFINITIONS/TY  Itomated drug  ther than composite of the compos	PE OF ADDS DE delivery system ounding or admos, shall collect, ment of drugs in	VICE USED  n," a mechanical inistration, relation and out of the	715.1(b)(3 system the ve to stora ntain all tr	at performs operation age, dispensing, or ansaction informatio
	□ Completing location of  FOR ALL TYPE  SECTION 1: D  An ADDS – "A  or activities of distribution of to accurately the section of the sectio	a self-assessman ADDS to a note of ADDS: CO  EFINITIONS/TY  Itomated drug  ther than composite of the compos	PE OF ADDS DE delivery system ounding or admos, shall collect,	VICE USED  n," a mechanical inistration, relation and out of the	715.1(b)(3 system the ve to stora ntain all tr	at performs operatio age, dispensing, or ansaction informatio
	□ Completing location of  FOR ALL TYPE  SECTION 1: D  An ADDS – "A  or activities of distribution of to accurately the section of the sectio	a self-assessman ADDS to a note of ADDS: CO  EFINITIONS/TY  Itomated drug  ther than composite of the compos	PE OF ADDS DE delivery system ounding or admos, shall collect, ment of drugs in	VICE USED  n," a mechanical inistration, relation and out of the	715.1(b)(3 system the ve to stora ntain all tr	at performs operation age, dispensing, or ansaction informatio
	Completing location of some section of section 1: D An ADDS – "A or activities of distribution of to accurately the and accountable section of the section o	a self-assessman ADDS to a note of ADDS: CO  EFINITIONS/TY  Itomated drug  her than composite of the composi	PE OF ADDS DE delivery system ounding or adm DS, shall collect, ment of drugs in 9.11(b)(1), 4017	VICE USED  n," a mechanical inistration, relation and out of the	715.1(b)(3 system the ve to stora ntain all tr	at performs operation age, dispensing, or ansaction informatio
lo N/A	Completing location of some section of section 1: D An ADDS – "A or activities of distribution of to accurately the and accountable section in the section of the section o	an ADDS to a nan ADDS: CO  FINITIONS/TY  Itomated drug  ther than composite than composite the mover area and the composite the composite than the composite than the composite that the composi	PE OF ADDS DE delivery system ounding or adm DS, shall collect, ment of drugs in 9.11(b)(1), 4017	VICE USED  n," a mechanical inistration, relation and out of the	715.1(b)(3 system the ve to stora ntain all tr	at performs operatio age, dispensing, or ansaction informatio
√o N/A	Completing location of location of section 1: D An ADDS – "A or activities of distribution of to accurately to and accountable identification in the section is and accountable identification in the section is and accountable identification in the section is an accountable identification in the section is an accountable identification in the section is an accountable identification in the section is a section in the section in the section is a section in the section in the section is a section in the section in the section is a section in the section in the section is a section in the section in the section in the section is a section in the section in the section in the section is a section in the section in the section in the section is a section in the sectio	a self-assessman ADDS to a nan ADDS: CO  FINITIONS/TYP  Itomated drug  ther than composite than composite the mover area the mover area to the mover area. [BPC 4119]	PE OF ADDS DE delivery system ounding or adm DS, shall collect, ment of drugs in 9.11(b)(1), 4017	VICE USED  n," a mechanical inistration, relaticontrol, and maito and out of the (3(a)]	system the ve to stora ntain all trespondent for system for the system system for the system system for the system system for the system	at performs operatio age, dispensing, or ansaction informatio
No N/A	Completing location of location of section 1: Description of the accountable in the pharm of	a self-assessman ADDS to a nan ADDS: CO EFINITIONS/TYINITIONS/TYINITIONS AN ADD drugs. An ADD rack the mover illity. [BPC 4119] TYPE OF ADDS Tacy uses an AP	PE OF ADDS DE delivery system ounding or adm DS, shall collect, ment of drugs in 9.11(b)(1), 4017  DEVICE USED	VICE USED  n," a mechanical inistration, relaticontrol, and maito and out of the (3(a))	system the ve to stora ntain all treesystem for system for each system for eac	at performs operation age, dispensing, or ansaction information or security, accuracy, accuracy, an ADDS for
Io N/A	Completing location of location of section 1: D An ADDS – "A or activities of distribution of to accurately to and accountable in the section of the location in the location	a self-assessman ADDS to a nan ADDS: CO  FINITIONS/TYLE  Itomated drug  ther than composite them than composite them are the mover ack the mover ack the mover than the spensing of presenting of presenting and AP aspensing of present and AP aspension and AP aspen	PEOF ADDS DE delivery system ounding or adm DS, shall collect, ment of drugs in P.11(b)(1), 4017  DEVICE USED  PDS – "Automate escribed drugs delivery and delivery system of drugs in P.11(b)(1), 4017	VICE USED  n," a mechanical inistration, relaticontrol, and maito and out of the (3(a)]	system the ve to stora ntain all treesystem for system for each system for eac	at performs operation age, dispensing, or ansaction information or security, accuracy, accuracy, an ADDS for

	1.2 The pharmacy uses an AUDS – "Autor and retrieval of unit dose drugs for admit these functions. [BPC 4119.11(b)(3), 401]	nistration to patient by person	_
	1.3 The pharmacy uses an <b>AUDS – "Autor</b> and retrieval of unit dose drugs for admir drug room or hospital emergency room varied by the second	nistration and dispensing to pa	ntients by a physician in a
	<b>SECTION 2: LOCATION OF DEVICES</b>		
Yes No N/A	2.1 Provides pharmacy services to the pa for discount drug programs under federa defined. The APDS need not be at the sa the specific conditions are met. "Covere United Sates Code. [BPC 4119.11(a) (a)(1)	I law as specified through the me location as the underlying d entity" as defined by section	use of an APDS as operating pharmacy if all
	2.2 Provides pharmacy services through a of the pharmacy holding the ADDS licens		secured pharmacy area
	2.3 Provides pharmacy services through a section 1250 of the Health and Safety Co section 1261.6 of the Health and Safety C	de <u>(HSC)<del>(Long Term Care (LTC)</del></u>	that complies with
Yes No N//	2.4 Provides pharmacy services through <u>a</u> 1204.1 of the Health and Safety Code, or 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 regularly seen for purposes of diagnosis a dangerous drugs and dangerous devices 4427.6(j)]	and treatment, and the APDS i	s only used to dispense
	2.7 <u>AUDS operated by a licensed hospita</u> and <u>Professions Code</u> , and is used solely licensed general acute care hospital facili defined in subdivision (a) and (b) of sectiexempt from the requirement of obtaining owns or leases the AUDS and owns the data The AUDS shall comply with all other requirement of professions Code. The licensed hospital complements of the professions Code.	to provide doses administered ity or a licensed acute psychiat on 1250 of the Health and Safe ng an ADDS license, if the licen angerous drugs and dangerous uirements for an ADDS in Artic	to patients while in a cric hospital facility, as ety Code, shall be sed hospital pharmacy s devices in the AUDS. Cle 25 of the Business
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> <u>2</u> 23)	Page 3 of 45	PIC Initials

	each AUDS it operates and shall make the list available to the board upon request. [BPC 4427.2(i)]
	4427.2(1)]
	2.8 AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room), as
	defined in section 4056 of the Business and Professions Code, and is used to provide doses
	administered to patients while in a licensed general acute care hospital and to dispense drugs
	to outpatients if the physician determines that it is in the best interest of the patient that a
	particular drug regimen be immediately commenced or continued, and the physician
	reasonably believes that a pharmacy located outside the hospital is not available and accessible
	at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical
	services or within a 30-mile radius. The quantity dispensed is limited to an amount necessary
	to maintain uninterrupted therapy and does not exceed a 72-hour supply. [BPC 4056, 4427.2(i)]
Yes No N/A	
	2.9 AUDS located in the emergency room operated by a licensed hospital pharmacy, as defined
	in subdivisions (a) and (b) of section 4029 of the Business and Professions Code, and is used to
	provide doses administered to patients while in a licensed general acute care hospital facility or
	a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of section
	1250 of the Health and Safety Code, and to dispense to an emergency room patient if: [BPC
	4068, 4427.2(i)]
	2.9.1. The hospital pharmacy is closed and there is no pharmacist available in the
	hospital.
	2.9.2. The drug is acquired by the hospital pharmacy.
	2.9.3. The dispensing information is recorded and provided to the pharmacy when the
	pharmacy reopens.
	☐ 2.9.4. The hospital pharmacy retains the dispensing information and controlled
	substances dispensing information is reported to the Department of Justice pursuant to
	section 11165 of the Health and Safety Code.
	2.9.5. The prescriber determines it is in the best interest of the patient that a particular
	drug regimen be immediately commenced or continued and the prescriber reasonably
	believes a pharmacy located outside the hospital is not available and accessible at the
	time of dispensing to the patient.
	2.9.6. The quantity is limited to an amount necessary to maintain uninterrupted
	therapy, but shall not exceed a 72-hour supply.
	Note: Licensure of AUDS operated under these provisions is required.
	2.10 A facility licensed in CA with the statutory outhority to provide pharmacoutical comices
<u> </u>	2.10 A facility licensed in CA with the statutory authority to provide pharmaceutical services.
	[BPC 4427.65(a)(1)] Type of Facility:
	<u>Type of Facility:</u> Statutory authority to provide pharmaceutical services (List code section):
	Statutory authority to provide pharmaceutical services (List code section).
	2.11 Jail, youth detention facility, or other correctional facility where drugs are administered
	within the facility under the authority of the medical director. [BPC 4427.3(b)(6), BPC
	4427.65(a)(2)]
	Type of Facility:

Page 4 of 45

PIC Initials \_\_\_\_\_

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>23</u>)

	licensed p	te: An ADDS license is not requ remises area of a pharmacy, u ous drugs and dangerous devic	ised in the selecting, counting,	
es No N//	(Answer N A 3.1 The AD	B: GENERAL REQUIREMENTS F  I/A if licensure not required)  DDS is installed, leased, owned,  I.2(a), 4427.4(a)]		is licensed by the board.
es No N/A	3.2 The AD	DS license was issued to a hold located and licensed in Califor		ve pharmacy license of a
	3.3 Each Al	DDS has a separate license. [BP	C 4427.2(c)]	
	3.4 The lice	ensed ADDS meets the followin	g conditions: [BPC 4427.2(d)]	
<del>(es No N//</del>	☐ 3.4.1 ☐ 3.4.2 ☐ 3.4.3 ☐ 3.4.4	The proposed location for instance section 4427.3 and the ADDS individuals.  The pharmacy's policies and posecurity measures and monitor the pharmacy's policy and produce losses from the ADDS investigation.	tallation of the ADDS meets the secure from access and removed access and removed accedures related to the ADD pring of the inventory to preven accedures include provisions for entory, as required by law.	S include appropriate ent theft and diversion. or reporting to the board
	ADDS licer	censure inspection was conductions at the proposed location(s) are at the proposed location(s) of pre-license inspection (s):		eted application for the
	3.6 The pha [BPC 4427	armacy is aware a relocation of .2(e)]	f an ADDS shall require a new	application for licensure.
	•	narmacy is aware a replacemen days. [BPC 4427.2(e)]	t of an ADDS shall require not	ification to the board
	-	armacy is aware the ADDS licer g pharmacy license is not curre		
	17M-112 (	(Rev. 1 <del>2</del> / <del>18</del> <u>223</u> )	Page 5 of 45	PIC Initials

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

	of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]
	3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]
	3.10 The ADDS license(s) is/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]
	3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]
Yes No N/A	3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]
	3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)] 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC section 4008.  [BPC 4427.4(c)]
	3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d), 4119.11(a)(3)]
	3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]
	3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), $4427.65(c)(5)(D)$ , HSC $1261.6(f)(4)$ ]
	3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), BPC 4427.65(c)(5)(D), BPC 4119.11(f), HSC 1261.6(f)(5)]

	3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under section 4427.3 of the Business and Professions Code, and, upon retrieval of the dangerous drugs and dangerous devices from the secured storage, is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]
	3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]
Yes No N/	3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.  [BPC 4427.7(b), BPC 4427.7(b), BPC 4119.11(j)]
	3.22 The record of quality assurance review, as provided in California Code of Regulation section 1711(e), is immediately retrievable in the pharmacy for at least one year from the date the record was created. [CCR 1711(f)]
	3.23 An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the pharmacy's license. [CCR 1711 (e), CCR 1711(f)]
	3.24 The PIC of EACH ADDS completes a self-assessment of the pharmacy's compliance with
	federal and state pharmacy law and is performed [CCR 1715.1(a), (b)]:
	<ul> <li><u>Before July 1-of every odd-numbered year.</u></li> <li>Within 30 days whenever a new ADDS licensed has been issued.</li> </ul>
	• Within 30 days when there is a change in PIC.
	<ul> <li>When there is a change in the licensed location of an ADDS to a new address.</li> </ul>
	3.25 The PIC of an ADDS assesses the system's compliance with current laws and regulations by
	using the components of Form 17M-112 (Rev 1/22) entitled "Automated Drug Delivery System Self-Assessment." [CCR 1715.1(c)]
	3.26 The PIC responds "yes", "no", or "not applicable" about whether the ADDS is, at the time of
	the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting. [CCR 1715.1(c)(2)]

	3.27 For each "no" response, the PIC provides a written corrective action or action plan to come
	into compliance with the law. [CCR 1715.1(c)(3)]
	3.28 The PIC initialed each page of the self-assessment with original handwritten initials in ink or
	digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form.
	(CCR 1715.1(c)(4))
	3.29 The PIC has certified on the last page of the self-assessment that they are the PIC, has
	certified a timeframe within which any deficiency identified within the self-assessment will be
	corrected, and has acknowledged all responses are subject to verification by the Board of
	Pharmacy. The certification is made under penalty of perjury of the laws of the State of
	California and the information provided in the self-assessment form is true and correct with an
	original handwritten signature in ink or digitally signed in compliance with Civil Code Section
	1633.2(h) on the self-assessment form. [CCR-1715.1(c)(5)]
Yes No N//	<u> </u>
	3.30 The ADDS owner has certified the final page of the self-assessment that they have read and
	reviewed the completed self-assessment and acknowledges that failure to correct any deficiency
	<u>identified in the self-assessment could result in the revocation of the ADDS license issued by the</u>
	Board. The certification is made under penalty of perjury of the laws of the State of California
	with an original handwritten signature or digitally signed in compliance with Civil Code Section
	1633.2(h) on the self assessment form. [CCR 1715.1(c)(6)]
	-3.31 Each self-assessment is completed in its entirety and kept on file in the underlying pharmacy
	<u> </u>
<u>———</u>	for three (3) years after it is performed. The completed, initialed, and signed original is readily
	<u> </u>
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  = 3.33.1 All controlled substances added to an ADDS are accounted for.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  = 3.33.1 All controlled substances added to an ADDS are accounted for.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  1.33.1 All controlled substances added to an ADDS are accounted for.  1.33.2 Access to the ADDS is limited to authorized facility personnel.  1.33.3.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment.  [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  = 3.33.1 All controlled substances added to an ADDS are accounted for.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  3.33.1 All controlled substances added to an ADDS are accounted for.  3.33.2 Access to the ADDS is limited to authorized facility personnel.  3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.  3.33.4 Confirmed losses of controlled substance are reported to the board.
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  3.33.1 All controlled substances added to an ADDS are accounted for.  3.33.2 Access to the ADDS is limited to authorized facility personnel.  3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.  3.33.4 Confirmed losses of controlled substance are reported to the board.  3.24 The pharmacy's inventory reconciliation report prepared at least once every three months
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  3.33.1 All controlled substances added to an ADDS are accounted for.  3.33.2 Access to the ADDS is limited to authorized facility personnel.  3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.  3.33.4 Confirmed losses of controlled substance are reported to the board.  3.24 The pharmacy's inventory reconciliation report prepared at least once every three months for federal Schedule II controlled substances, includes the federal Schedule II controlled
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]  3.33.1 All controlled substances added to an ADDS are accounted for.  3.33.2 Access to the ADDS is limited to authorized facility personnel.  3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.  3.33.4 Confirmed losses of controlled substance are reported to the board.  3.24 The pharmacy's inventory reconciliation report prepared at least once every three months
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]   \$\Begin{array}{cccccccccccccccccccccccccccccccccccc
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]   3.33.1 All controlled substances added to an ADDS are accounted for.  3.33.2 Access to the ADDS is limited to authorized facility personnel.  3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.  3.24 The pharmacy's inventory reconciliation report prepared at least once every three months for federal Schedule II controlled substances, includes the federal Schedule II controlled substances stocked in the ADDS. (CCR 1715.65[a][1])  3.25 The pharmacy's inventory reconciliation report prepared at least once every 12 months for
	for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]  3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]  3.33 The PIC ensures the following: [CCR 1715.65(h)]   \$\Begin{array}{cccccccccccccccccccccccccccccccccccc

Page 8 of 45

PIC Initials \_\_\_\_\_

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>2</u>3)

6.25mg/10mg/5ml, includes these controlled substances stocked in the ADDS. (CCR 1715.65([a][2])
3.26 Inventory activities are performed at least once every two years from the performance of the last inventory activities for each controlled substance that is not listed as a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml and includes the controlled substances stocked in the ADDS. (CCR 1715.65[a][3][B])
3.27 For any controlled substance stocked in the ADDS that is not a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, the pharmacy prepares an inventory reconciliation report for the identified loss of that controlled substance in the ADDS no later than three months after the discovery of the reportable loss and is completed if the loss is discovered either by the inventory activities or any other manner. (CCR 1715.65[a][3][A])
3.28 A physical count, not an estimate, of the federal controlled substances in the ADDS is taken for the inventory reconciliation reports, except for an inpatient hospital pharmacy or correctional pharmacy where the inventory in the ADDS may be accounted for using means other than a physical count. (CCR 1715.65[c][1], CCR 1715.65[h])
3.29 The PIC or the consulting pharmacist for a clinic (BPC 4180 or 4190) reviews all inventory activities performed and inventory reconciliation reports prepared in accordance with CCR 1715.65 and has established and maintained secure methods to prevent losses of federal controlled substances. (CCR 1715.65[b])
3.30 The pharmacy has written policies and procedures developed for performing the inventory activities and preparing the inventory reconciliation reports in accordance with CCR 1715.65 that includes the inventory of federal controlled substances stored in the ADDS. (CCR 1715.65)
3.341 The original board-issued ADDS permit and current renewal are posted at the ADDS premise, where they may be clearly read by the public. [BPC 4058]
CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Page 9 of 45

PIC Initials \_\_\_\_\_

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<del>2</del>3)

Please Note: The Pharmacist-in-Charge of the pharmacy and the <u>pharmacy</u> owner <u>or hospita administrator</u> of the ADDS shall sign the Certification Acknowledgment on page 33 48 after completing the assessment.
<ul> <li>□ SECTION 4: —APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.</li> <li>□ SECTION 5: —ADDS</li> <li>■ APDS adjacent to the secured pharmacy area (or)</li> <li>■ APDS located in a Medical Offices (or)</li> <li>■ APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice (or)</li> <li>■ APDS located at a clinic pursuant to HSC 1204, HSC 1204.1, BPC 4180, or BPC 4190.</li> </ul>
<ul> <li>□ SECTION 6: =ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6.</li> <li>□ SECTION 7 = APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190</li> <li>□ SECTION §7: – ADDS operated by a correctional clinic pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).</li> <li>□ SECTION §8:</li> <li>• Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 (when the hospital pharmacy is closed and no pharmacist is available).</li> <li>• Drug Room: AUDS used for dispensing pursuant to BPC 4056.</li> </ul>
<ul> <li>SECTION 9:         <ul> <li>AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)</li> <li>AUDS through a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).</li> </ul> </li> </ul>
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 cover published by the Health Resourby Board during normal business h	ces and Services Administration	
	4.3 Drugs purchased and receive ( <u>USC)</u> shall be segregated from means. [BPC 4126(b)]	•	
Yes No N/	4.4 All records of acquisition and separate from the pharmacy's c		be readily retrievable in a form
	4.5 The drugs shall be returned to be dispensed to patient of a coordistributed because of a change [BPC 4126(c)]	vered entity pursuant to section	256b of Title 42 USC cannot be
	4.6 A licensee that participates in this section shall not have both		
	CORRECTIVE ACTION OR ACTION	N PLAN AND COMPLETION DATE	<u></u>
Yes No N/	B. UNDERLYING OPERATIN	IG PHARMACY	
	4.7 The operating pharmacy has includes the address of the APD site. [BPC 4119.11(a)(1)]	obtained a license from the Boa S location and the identity of the	
	4.8 A separate license was obtair concurrent with the pharmacy l APDS at an address for which th 4119.11(a)(8), 4107]	icense. (Note: The Board may iss	sue a license for operation of an
	4.9 A prelicensure inspection of 30 days after Board receipt of the	the proposed APDS location was ne APDS application before Boar	•
	Date of Inspection:		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 11 of 45	PIC Initials

	4.10 The pharmacy will submit a new APD current APDS is relocated. [BPC 4119.11(		ard approval if the	
	4.11 The pharmacy will notify the Board w discontinuing an APDS. [BPC 4119.11(a)(9)	vithin 30 days of replacement	of an APDS or	
	4.12 A new APDS licensure application will underlying operating pharmacy's permit (Once cancelled, a new APDS license can reissued or reinstated.) [BPC 4119.11(a)(	being cancelled, not current, only be issued if the underlyi	not valid, or inactive.	
Yes No N//	4.13 The pharmacy does not have more the pharmacy under this section. [BPC 4119.2			
	1	2		
	3	4		
	5	6		
	7	8		
	9	10		
	11	12		
	13	14		
	15			
Yes No N//	4.14 The operating pharmacy will maintai after the last date of use for that APDS. [I	•	•	
	4.15 The operating pharmacy of an APDS pursuant to CCR 1715.1 or BPC 4427.7(a) law relating to the use of the APDS. [BPC	evaluating the pharmacy's co		
	Date of Last Self-Assessment:	nange in PIC;	cation of ADDS	
	4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]			
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 12 of 45	PIC Initials	

	4.17 The pharmacy is aware that the dr	<del>ugs stored in an APDS a</del>	re a part of the operating
	pharmacy's drug inventory and the dru	igs dispensed by the AP	DS shall be considered to have
	been dispensed by that pharmacy. [BP4	<del>C 4119.11(a)(3)]</del>	
	4.1 <u>86</u> The underlying operating pharma	cy is solely responsible	for: [BPC 4119.11(a)(5), (6)]
	☐ 4.16.1 The security of the APDS. [B☐ 4.16.2 The operation of the APDS. ☐ 4.16.3 The maintenance of the APD ☐ 4.16.4 The training regarding the orange and covered entity personn	[BPC 4119.11(a)(5)] OS. [BPC 4119.11(a)(5)] peration and use of the	•
	CORRECTIVE ACTION OR ACTION PLAN	AND COMPLETION DA	ΓΕ:
	·		
	C. PHARMACIST RESPONSIBILITIE	S	
Yes No N/A			to a consideration and the constant and
	4.1 <u>97</u> The operation of the APDS is undobehalf of the operating pharmacy. [BPO physically present at the site of the API	C 4119.11(a)(7)]. Note:	The pharmacist need not be
	4. <del>20</del> 18 The pharmacist performs the sto pockets, cards, drawers, similar techno the stocking of the APDS may be done [BPC 4119.11(g)]	logy, or unit of use or s	ingle dose containers are used,
	4. <del>20</del> 18.1 A pharmacist, intern phase supervision of the pharmacist may similar technology, or unit of use or	place drugs into the rer	moveable pockets, cards, drawers,
	4. <del>20</del> 18.2 Transportation of remove unit of use or single dose container evident container. [BPC 4119.11(g)]	veable pockets, cards, does between the pharmac	lrawers or similar technology <u>o</u> ⊖r
	☐ 4. <del>20</del> 18.3 There are policies and p drawers, similar technology, or unit the APDS. [BPC 4119.11(g)(3)]	rocedures to ensure the	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 13 of 45	PIC Initials

	4.2119 The A pharmacist conduct of the drugs contained within, or review of all transaction records [BPC 4119.11(h)]	peration, maintenance, and clea	anliness of the APDS, and a
	Date of Last Review:		
	4. <del>22</del> 20 The Pharmacist-in-charge [CCR 1715.65(h)]	of the offsite ADDS/APDS has e	ensured the following:
	4.20.1 All controlled substant 4.20.2 Access to ADDS/APDS 4.20.3 An ongoing evaluation substance is performed 4.20.4 Confirmed losses of confirmed	n of discrepancies or unusual aced; and	personnel; ccess associated with controlled
	CORRECTIVE ACTION OR ACTION	PLAN AND COMPLETION DATE	:
	D. DEVICE REQUIREMENTS		
Yes No N/		assword shall include a camera	that records a picture of the
	4.24 The APDS makes complete a	nd accurate records of all trans	actions including users
	4.2 <u>52</u> The APDS will collect, contr the movement of drugs into and	ol, and maintain all transaction	information to accurately track
	4.2 <del>6</del> 3 The APDS will maintain transformat for review and inspection [BPC 4119.11(c)(2)]		
	4.2 <u>¥4</u> The APDS may dispense me [BPC 4119.11(d)]	dications <b>DIRECTLY</b> to the pation	ent if <b>all</b> the following are met:
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 14 of 45	PIC Initials

	171	<b>M-112</b> (Rev. 1	<del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 15 of 45	PIC Initials
		devices dispe	nsed from the A ia telecommunic	PDS. The consultation shall b	time on all prescribed drugs and be provided by a Board-licensed audio and video capabilities. [BPC
		after the pha	rmacist has revie		thorization from the pharmacist e patient's profile for potentials
		4.2 <del>7</del> <u>4</u> .4 The p	=	erformed all clinical services	as part of the dispensing process <u>.</u> onsultation. [BPC 4119.11(d)(4)]
<del>lo N//</del>	<u>.</u>	identified pat	tient's drugs and	devices to the patient or the	ch patient and only release the patient's agent. [BPC
		4.2 <u>₹4</u> .2 The Ademonstrating APDS. Attach	ng their informed	e used for patients who have I consent to receive prescribe nsent form to the back of the	ed drug <u>s</u> and devices from the
			from the APDS	in the event <u>that</u> the APDS is	to patients expecting medications s disabled or malfunctions.
			Orienting patie medications ar use of the APD	e not available in the APDS. <sup>-</sup> S does not interfere with the	notifying patients when expected The pharmacy must ensure the e delivery of drugs and devices.
		<u>4.24.1.4</u>	L Describing assi	gnment of responsibilities ar	ncluding those delivered via APDS <u>.</u> nd training of pharmacy personnel, : location <u>.</u> regarding maintenance
		<u> </u>	patients <u>, includ</u>	oropriate for placement in th ding when consultation is nee nts are aware that consultation	<u>eded.</u>
		<u> </u>		and apply <u>ing</u> inclusion criter	ia regarding which drugs <u>, and</u>
				e security of the APDS and da	angerous drug and devices
		policies and p	procedures with	developed <u>,</u> <del>and</del> implemente respect to all the following a <del>(d)(1)(F)</del> , CCR 1713(e)]	<u> </u>

		$4.2\overline{+4}$ .7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]
		$4.2\frac{74}{2}$ .8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]
	4.2	7.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the
		armacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]
	4.2	The federal warning label prohibiting transfer of controlled substances is on the escription container. [21 CFR 290.5]
Yes No N/A	4	
	ор	Pecape Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of- ening tested container, or in a non-complying package only pursuant to the prescriber or then requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
	4. <del>3</del> 4	Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
		$\frac{1}{28}$ The pharmacy provides patients with Black Box Warning Information in conformance th 21 CFR 201.57(c).
	4. <del>3.</del>	<u>229</u> Medication guides are provided on required medications. [ <u></u> €21 CFR 208.1] →
		O The pharmacy uses the APDS to deliver prescription medications to patients as provided: CR 1713(d)]
		4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.
		4.30.2 The APDS has a means to identify each patient and only release the patient's
		prescription medications to the patient or patient's agent.
		4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-
	_	person or via telephone, upon the request of a patient.
	Ш	4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has
		occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
	CO	RRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	_	
	_	

# **E. RECORD KEEPING REQUIREMENTS** Yes No N/A 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(i)] $\square \square$ $\square$ 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)] $\Box\Box\Box$ 4.3 $\frac{1}{2}$ Any records maintained electronically must be maintained so that the pharmacist-incharge, 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 $\square$ $\square$ 4.362 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually [BPC 4119.11(d)(1), CCR <u>1713(e)</u>]: ☐ 4.32.1 Maintaining the security of the APDS and dangerous drugs and devices within the APDS. 4.32.2 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients, including when consultation is needed. ☐ 4.32.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS. ☐ 4.32.4 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS. 4.32.5 Orienting patients on use of the APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices. 4.32.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event if the APDS is disabled or malfunctions.

		Date of Last Policy Review:
		The pharmacy has policies and procedures for security measures and monitoring of the ory to prevent theft and diversion. [BPC $\frac{4427.2(d)(3)}{4105.5(c)(2)}$ ]
	_	The pharmacy reports drug losses as required by law. [BPC 4104, <u>4427.2(d)(4)</u> 4 <del>105.5(c)</del> , 715.6, 21 CFR 1301.76]
	Last Re	eported Drug Loss:
	CORRE	ECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
		NUE ADDO
		ON 5: ADDS  APDS ADJACENT TO THE SECURED PHARMACY AREA OR  APDS LOCATED IN MEDICAL OFFICES (OR)  APDS A LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS
		AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE (OR)  APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.
Yes No N/A		GENERAL REQUIREMENTS
	5.1 Th	e pharmacy maintains the APDS policies and procedures for 3 years after the last date of r that APDS. [BPC 4427.6(I) <u>. CCR 1713(f)</u> ]
		e pharmacy developed and implemented, and reviewed annually the APDS policy and stures pertaining to the APDS, including: [BPC 4427.6(a)]
	•	-Maintaining the security of the APDS and the dangerous drugs and devices within the
	•	Determining and applying inclusion criteria regarding which drugs and devices are
	_	appropriate for placement in the APDS and for which patients.  Ensuring patients are aware consultation with a pharmacist is available for any
		prescription medications, including those delivered via the APDS.
	•	Describing assignment of responsibilities to, and training of, pharmacy personnel and
		other personnel using the APDS at the location where the APDS is placed, regarding
		maintenance and filing procedures for the APDS.
	•	Orienting participating patients on the use of the APDS, notifying patients when
		expected prescription medications are not available in the APDS, and ensuring patient
		use of the APDS does not interfere with delivery of drugs and devices.
	•	Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

	5.2 The pha	rmacy uses the APD	S to deliver prescription medicati	ons to patients provided: [CCR
	<u>1713(d)]</u>			
	<u> 5.2.1</u>	criteria for use of t	determined that each patient using the APDS established by the pharmation to the patient.	
	<u>□</u> <u>5.2.2</u>	The APDS has a me	eans of identifying each patient are eation to the patient or patient's a	
	<u> </u>		vides an immediate consultation whone, upon the request of a patie	
	<u> 5.2.4</u>	Any incident involvoccurred shall be r	ving the APDS where a complaint, eviewed as part of the pharmacy ness and Professions Code section	delivery error, or omission has 's quality assurance program
Yes No N/A	A			
	pharmacy u	nder this section. [B	e more than 15 APDS licenses for BPC 4427.6(k)] List of current APD 2.	S licenses:
	3		4	·
	5		6	
	7		8	
	9		10	
	11		12	
	13		14	
	15			
	CORRECTIVE	E ACTION OR ACTIO	N PLAN AND COMPLETION DATE_	
B. PHAR	RMACIST RES	PONSIBILITIES:		
	<b>17M-112</b> (R	ev. 1 <del>2</del> / <del>18</del> <u>223</u> )	Page 19 of 45	PIC Initials

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/F	5.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. All prescribed drugs and devices dispensed to the patient from the APDS for the first time are accompanied by a consultation conducted by a California licensed pharmacist. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]
Yes No N//	5.7 The <u>Pp</u> harmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]
	<ul> <li>5.7.1 All controlled substances added to the ADDS/APDS are accounted for;</li> <li>5.7.2 Access to ADDS/APDS is limited to authorized facility personnel;</li> <li>5.7.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and</li> <li>5.7.4 Confirmed losses of controlled substances are reported to the Board.</li> </ul>
	5.8. The pharmacy operating the APDS has completed an <u>annual Self-Assessment pursuant to</u> CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the <u>APDS. [BPC 4427.7(a)]</u>
	Date of Last Self-Assessment:
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	C. DEVICE REQUIREMENTS:
Yes No N//	
	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
	,

	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/	5.148 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS.  Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]
	5.459 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. <u>4610</u> 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. <del>17</del> 11 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]
	5. <u>1812</u> 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. <u>1913</u> 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. <del>20</del> 14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

	of-opening tested container, or	sed in a new and child-resistant in a non-complying package only er. [15 USC 1473[b], 16 CFR 1700	pursuant to the prescriber or
	5. <del>22</del> 16 Patient package inserts	are dispensed with all estrogen r	nedications. [21 CFR 310.515]
	5. <del>22</del> 17 The pharmacy provides with 21 CFR 201.57(c).	patients with Black Box Warning	Information in conformance
	5. <del>24</del> 18 Medication guides are p	rovided on required medications	s. [21 CFR 208.1]
	CORRECTIVE ACTION OR ACTION	N PLAN AND COMPLETION DATE	
Yes No N/	D. RECORD KEEPING RE	QUIREMENTS	
		s-complied with all recordkeepin	g and quality assurance
	1 01 1	427.6 and those records shall be	0 1 1
	- 1	recor record the other pharmacy record	ds. [BPC 4427.7(b)]
	5. <u>2619</u> The operating pharmacy dangerous drugs stored in the A	will maintain records of acquisiti PDS separate from other pharm	-
	during which the licensed prem	ty if the pharmacist-in-charge is ses are open for business, be ab acquisition and disposition or ot	not on duty, must, at all times le to produce a hardcopy and
	CORRECTIVE ACTION OR ACTION	N PLAN AND COMPLETION DATE	
Vac Na N//	E. POLICIES AND PROC	EDURES	
Yes No N/A	5. <del>28</del> 21 The pharmacy has develo	the policies are <u>maintained and</u> r	
	$\underline{\Box}$ <u>5.21.1</u> Maintaining the	security of the APDS and dangero	ous drug and devices within the
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 22 of 45	PIC Initials

	APDS <u>.</u>	
	$\square$ 5.21.2 Determining and applying inclusion criteria regarding which drugs and devices	,
	are appropriate for placement in the APDS and for which patients.	
	<u>5.21.3</u> Ensuring patients are aware that consultation with a pharmacist is available for	
	any prescription medication including those delivered via APDS.  5.21.4 Describing assignment of responsibilities and training of pharmacy personnel	
	and other personnel using the APDS at that location regarding maintenance and	
	filling procedures for the APDS.	
	☐ 5.21.5 Orienting patients on use of APDS and notifying patients when expected	
	medications are not available in the APDS. The pharmacy must ensure the use of	i
	the APDS does not interfere with the delivery of drugs and devices.	
	<u> 5.21.6</u> 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:	
es No N/A		_
	5.29 The pharmacy reports drug losses as required by law. [BPC 4104, $4427.2$ (d)(4) $4105.5$ (e),	
	CCR 1715.6, 21 CFR 1301.76]	
	Look Domontod Dwig Loos	
	Last Reported Drug Loss:	
	CORRECTIVE A CTION OR A CTION RIAN AND COMPLETION RATE	
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE	-
		-
		_
	SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 — LONG TERM CARE	
	SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 — LONG TERM CARE  FACILITIES THAT COMPLIES WITH HSC 1261.6	
	FACILITIES THAT COMPLIES WITH HSC 1261.6	
	FACILITIES THAT COMPLIES WITH HSC 1261.6	
	A. GENERAL REQUIREMENTS	
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to	
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC \frac{1261.6(a)(2)-1250}{1250}]	
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and	
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician	•
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and	•
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2) 1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician [HSC 1261.6(a)(3)]	•
	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2) 1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician [HSC 1261.6(a)(3)]	•
es No N/A	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician [HSC 1261.6(a)(3)]	
es No N/A □-□-□-	A. GENERAL REQUIREMENTS  For purposes of this section, "FACILITY" means any health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)-1250]  For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician [HSC 1261.6(a)(3)]	

Page 23 of 45

PIC Initials \_\_\_\_\_

	maintenance of the ADDS as we	II as quality, potency, and purit	ty of the stored drugs and
	devices. [BPC 4427.3(c), HSC 126	<del>51.6 (d)(1)]</del>	
	6. <u>₹1</u> The ADDS policies and proceeding equipment and drugs. [HSC 126]		DS and limits to access to
	6.3 All ADDS policies and proced the ADDS is being used. [HSC 12	•	armacy and the location where
	6.42 The pharmacy is responsible operation and maintenance of t	_	d within the ADDS and the
	CORRECTIVE ACTION OR ACTION	N PLAN AND COMPLETION DAT	E
Yes No N/A	B. PHARMACIST RESPONS	IBILITIES:	
	6.53 The stocking of the ADDS is pockets, cards, drawers, similar the stocking system may be don following conditions are met: [8]	technology, or unit of use or si e outside the facility and be de	ngle dose containers <del>are used</del> , elivered to the facility if the
	use or single dose contai	ners is performed by a pharma	ockets, cards, drawers, or unit or acist, or by an intern pharmacist of a pharmacist. [BPC 4427.4(e)(1),
	<del>-</del>	the pharmacy and the facility	of use or single dose containers in a secure tamper-evident
	procedures to ensure that	ijunction with the pharmacy, hat the removable pockets, card re properly placed into the ADI	s, drawers, or unit of use or
Yes No N	$\frac{\sqrt{A}}{6.\frac{64}{2}}$ Individualized and specific a authorized by law to administer		o facility and contract personnel
	6. <u>₹5</u> A pharmacist reviews and a ADDS for administration to a parpatient's profile for potential co	tient. The pharmacist reviews t	the prescriber's orders and the
	6.6 A Schedule II controlled subsi		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 24 of 45	PIC Initials

	6.6.1 An orally transmitted prescription for a Schedule II controlled substance from the				
	prescriber and only after the pharmacist reduced the prescription to writing in ink in the				
	handwriting of the pharmacist on a form developed by the pharmacy. The prescription				
	must contain: [HSC 11167.5(a)]				
	☐ 6.6.1.1 The date the prescription was orally transmitted by the prescriber.				
	6.6.1.2 The name of the person for whom the prescription was authorized.				
		6.6.1.3	The name and address of the licensed skilled nursing facility or licensed		
			intermediate care facility in which the person is the patient.		
		6.6.1.4	The name and quantity of the controlled substance prescribed.		
		6.6.1.5	The directions for use, and the name, address, category of the		
			professional licensure, license number, and federal controlled substance		
			registration number of the prescriber.		
		6.6.1.6	The prescription is endorsed by the pharmacist with the pharmacy's		
			name, license number, and address.		
_	<u>6.6.</u>	2 Prior to	filling a prescription for a Schedule II controlled substance that has been		
	<u>elec</u>	ctronicall	y transmitted, the pharmacist has produced, signed, and dated a hard		
	<u>cop</u>	y prescri	otion. The prescription must contain: [HSC 11167.5(a)]		
		6.6.2.1	The date the prescription was electronically transmitted by the		
			prescriber;		
		6.6.2.2	The name of the person for whom the prescription was authorized;		
		6.6.2.3	The name and address of the licensed skilled nursing facility or licensed		
	intermediate care facility in which the person is the patient;				
		6.6.2.4	The name and quantity of the controlled substance prescribed;		
	☐ 6.6.2.5 The directions for use, and the name, address, category of the				
	professional licensure, license number, and federal controlled substant				
			registration number of the prescriber.		
		6.6.2.6	The prescription is endorsed by the pharmacist with the pharmacy's		
			name, license number, and address.		
		6.6.2.7	The prescription contains the signature of the person who received the		
			controlled substance for the licensed skilled nursing facility or licensed		
			intermediate care facility.		
	☐ 6.6.3 An original Schedule II prescription is written on a form that complies with Health				
	<u>and</u>	Safety C	ode section 11162.1. [HSC 11164(a)]		
	<u>6.6.</u>	4 An orig	inal Schedule II prescription is written with the "11159.2 exemption" for		
	the terminally ill. [HSC 11159.2]				

	6.6.5 In an emergency where failure to issue the prescription may result in loss of life
	or intense suffering, a Schedule II controlled substance may be dispensed from a
	prescription transmitted orally or electronically by a prescriber or written on a form
	not as specified in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]
	<ul> <li>☐ 6.6.5.1 The order contains all information required by subdivision (a) of Section 11164.</li> <li>☐ 6.6.5.2 If the order is written by the prescriber, the prescription is in ink, signed, and dated by the prescriber.</li> <li>☐ 6.6.5.3 If the prescription is orally or electronically transmitted, it must be reduced to hard copy.</li> <li>☐ 6.6.5.4 The prescriber provides a written prescription on a controlled substance</li> </ul>
	form that meets the requirements of HSC 11162.1 by the seventh day
	following the transmission of the initial order.
	☐ 6.6.6 An electronic prescription (e-script) for controlled substances that is received
	from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]
Yes No N/A	
	6.87 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6(h)]  Date of Last Review:
	6. <u>98</u> The <u>p</u> Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]
	<ul> <li>☐ 6.8.1 All controlled substances added to the ADDS are accounted for;</li> <li>☐ 6.8.2 Access to ADDS is limited to authorized facility personnel;</li> <li>☐ 6.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and</li> <li>☐ 6.8.4 Confirmed losses of controlled substances are reported to the Board.</li> </ul>
	6.109 The pharmacy operating the ADDS has completed an biennial Self-Assessment pursuant to BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS $\underline{}$ $\underline{}$ BPC 4427.7(a) $\underline{}$ .
	Date of Last Self-Assessment:
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

Yes No N/A	C. DEVICE REQUIREMENTS:
	6. $\frac{1410}{10}$ The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1), HSC 1261(c), (g)]
	6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS
	location are stored for no longer than 48 hours in a secured room within the ADDS location.
	Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect
_	any losses or overages. [BPC 4427.4(f)]
Yes No N/A	6. $\frac{13}{11}$ Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]
	6. <u>44</u> 12 The information required by BPC section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]
Voc No N/A	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)]:
	6.4513 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)]
	$6.\underline{4614}$ 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)]
	6.4715 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)]:
<del>Yes No N/A</del>	•

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>2</u>3)

Page 27 of 45

	$6.\underline{4816}$ 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)]
	6.1917 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)]
	6.2018 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6(f)(3)]
<u> </u>	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),
Yes No N/A	\
	6.2319 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)]
	6.2420 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)]
	6.2521 If the ADDS allows licensed personnel to have access to multiple drugs and are is not patient specific in its their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. $\{[HSC 1261.6(f)(7)]\}$ .
	<u>Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows</u> <u>licensed personnel to have access to multiple drugs is required to contact the California</u>
	<u>Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]</u>
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
<del>Yes No N/4</del>	D. RECORD KEEPING REQUIREMENTS

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>2</u>3)

Page 28 of 45

	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.
	<del>[BPC 4427.7(b)]</del>
Yes No N/A	
	6.2722 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)]
	ioi a minimum oi tinee years. [nsc 1201.0(b)]
	6.23 Records of inspections completed by the pharmacist are kept for at least three years.
	[HSC 1261.6(b), 22 CCR 70263(f)(3)]
	1130 1201.0(b), 22 00K 70203(1)(0)(1)
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	E. POLICIES AND PROCEDURES
Yes No N/A	
	6.2824 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. <del>29</del> 25 The ADDS policies and procedures define access to the ADDS and limits to access to
	equipment and drugs. [HSC 1261.6(d)(1)]
	- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
	6.3426 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)]
	6.3127 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)]
	6.3328 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			
	CECTION 7. ADDC TUDOUCU A	CLINIC DUDGLIANT TO LICC 120	LOD 4304 4 OD DDC 4400 OD	
	SECTION 7: APDS THROUGH A (	FINIC PURSUANT TO HISC 1204	<del>- OR 1204.1 OR BPC 4180 OR</del>	
	<del>4190</del>			
	A. GENERAL REQUIREMENT	<u>-c</u>		
<del>Yes No N</del>	<del>~ 3211211.21 11233112111211</del> <del>⊮A</del>	<del></del>		
	7.1 The ADDS is located inside an	enclosed building with a prem	ises address, at a location	
	approved by the Board [BPC 442			
	license pursuant to BPC 4180 or	` '-	•	
	<del>1204.1. [BPC 4427.3(b)(3)]</del>		•	
	<del>License number:</del>	Expiration Date	<u> </u>	
	7.2 The clinic has developed and	<del>implemented written policies a</del>	nd procedures that ensure the	
	safety, accuracy, accountability,	•	•	
	and procedures shall ensure the	, .	, , ,	
	The policies and procedures sha	• • • •		
	used. [BPC 4186(a)]			
	7.3 Drugs removed from the ADD	S shall he provided to the patic	ent hy a health professional	
	licensed pursuant to BPC 4186(b	•	me sy a meantri proressionar	
	membea parbaant to br e 1200(s	,.		
		e review of the drugs containe	d within, and the operation and	
	maintenance of, the ADDS. [BPC			
	7.5 Drugs dispensed from the clir	vic ADDS shall comply with labo	ling requirements in RPC 4076	
	with CCR 1707.5. [BPC 4186(g), 4	<del>1426.7(h)]</del>		
	20 2. 2. 10. [2. 2 . 120 (8))	(/)		
	7.6 The clinic shall keep records o	of the kind and amounts of drug	rs nurchased administered and	
	dispensed and the records shall			
	inspection by all authorized pers		a minimum or timee years for	
	mopeonion by an authorized pers	51111CH [21 6 1266(4)(2)]		
	7.7.The proposed ADDS installation	an location mosts the requirem	ent of BPC 4427.3 and the ADDS	
	is secure from access and remov	•		
	<del>із зесите поптассезз апи генно</del>	<del>аг әу анааспондеа ттатуғаата.</del>	<del>[DI C 11127.2(Q)(Z)]</del>	
	7.8 The clinics licensed under BPG		riodic inventory and inventory	
	reconciliation functions to detec		,	
	- community ramenous to detect	t and prevent the loss of control	The Januara Hoest	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 30 of 45	PIC Initials	
	T, IAI-TTE (IVCA, T <del>E</del> ) <del>TO</del> ( <del>TE</del> ∑)	1 agc 30 01 43	1 IC IIIItiais	

	<del>[CCR 1715.65(a)]</del>
	7.9 The clinic shall compile an inventory reconciliation report of all <b>federal Schedule II</b>
	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
	<ul> <li>A comparison of (1) and (2) to determine if there are any variances.</li> </ul>
	<ul> <li>All records used to compile each inventory reconciliation report shall be maintained at</li> </ul>
	clinic for 3 years in a readily retrievable form.
	<ul> <li>Possible causes of overages shall be identified in writing and incorporated into the</li> </ul>
	inventory reconciliation report.
	,
Yes No N/A	
	7.10 The clinic shall report in writing identified drug losses and known cause to the Board withir
	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, furthe
	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 fo
	<del>3 years. [CCR 1715.65(e)]</del>
	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.
	<del>[BPC 4427.6(i)]</del>
	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]
	7.45 Delice to a classic formula and discount of the effective and discount of the effective formula (1.50 Delice).
	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
	<del>21 CFR 201.57(c).</del>
	7.47 Madiantian suides and mustidad an naminal suidiation (24 CER 200.4)
	7-17 Medication guides are provided on required medications. [21 CFR 208.1]

Page 31 of 45

PIC Initials \_\_\_\_\_

devices to patients of the clinic? [BPC-7.19 Does the pharmacy have no more- List of current APDS licenses:		APDS units? [BPC 44
	than 15 ADDS licensed as	APDS UNITS 7 (BIFC 44
4		
	2	
±	<del></del>	
3	<del>4.</del>	
5.	6.	
<del>7</del>	<del>8.</del>	
9	10	
11.	12	
<del>13</del>	14	
<del>15.</del>		
B.—PHARMACIST RESPONSIBILITY	<u> </u>	
7-20 The pharmacist performs the stock	king of the ADDS. [BPC 416	<del>36(c)]</del>
7.21 Drugs are removed from the ADDS	System only upon the au	thorization of the pl
after the pharmacist has reviewed the	prescription and patient prescription and prescription	•
contraindications and adverse drug rea	actions. [BPC 4186(b)]	
7.22 The pharmacist shall conduct a rev	<del>riew on a monthly basis in</del>	<del>cluding a physical in</del>
the drugs in the ADDS for cleanliness a		<del>ion records in order</del>
_		
the security and accountability of the 4	ADDS. [BPC 4186(d)]	
_	<del>\DDS. [BPC 4186(d)]</del> 	

	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)]
	<del>[bi &amp; mz7.0(u)]</del>
Vac Na Ni	•
Yes No N/	
	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)]
	telecommunication link with a two-way addio and video. [br c ++27.0(1)]
	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)]
	and and trace telescommunication mint is: arage dispensed by the omnor is so [5]
	7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]
	7.26 THE PHAITHAUST OPERATING THE ADDS SHAILDE IOCATED III CAIHOTHIA. [DI C 4160(1)]
	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 POLICIEC AND DECCEPUES
	C.— POLICIES AND PROCEDURES
Yes No N/	
	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)]
	<ul> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the</li> </ul>
	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.
	(a) or seed of the tree regards and maintenance and mine processing for the tree bot

	APDS does not interfere with	delivery of drugs and devices.	
	• Ensuring delivery of drugs and		to receive them from the APDS
	in the event the APDS is disab	<del>led or malfunctions.</del>	
	Date of Last Policy Review:		
Yes No N/	4		
	7.33 Is the APDS only used for pat	ients who have signed a writte	n consent form demonstrating
		prescribed drugs and devices	· · · · · · · · · · · · · · · · · · ·
	of the APDS meets inclusion critic	<del>ria established by policies and</del>	procedures. [BPC 4427.6(b)]
	7.34 The APDS shall have a means	of identifying each patient and	dentified
	patient's drugs and devices to th		
	7.35 The pharmacy holding the Al	DDS license for an APDS maints	ins its policies and procedures
	for three (3) years after the last of		
	7.26 Doos the pharmacy maintain	all recordkeeping and quality	eccuranco roquiromente
	established in pharmacy law and		•
	pharmacy holding the ADDS licer	•	
	<del>[BPC 4427.7(b)]</del>		,
<u>SECTION</u>	<u>87</u> : ADDS OPERATED BY A CORR	ECTIONAL CLINIC	
	A. GENERAL REQUIREMENT	s	
Yes No N/		mated drug delivery system"	sod in a correctional clinic
	<u>7</u> €.1 The pharmacy uses an "automeaning a mechanical system coactivities, other than compoundidistribution of prepackaged dang delivery system shall collect, contrack the movement of drugs into accountability. [BPC 4187.5(h)]	ntrolled remotely by a pharma ng or administration, relative to serous drugs or dangerous devi trol, and maintain all transaction	cist that performs operations on the storage, dispensing, or ces. An automated drug on information to accurately
	<u>7</u> 8.2 The ADDS is located in a "co subdivision (b) of section 1206 of operated by the state to provide and Rehabilitation. <u>€</u> [BPC 4187 <u>(a)</u>	the Health and Safety Co <del>n</del> de, health care eligible patients of	conducted, maintained, or
¥es No N/A	78.3 The correctional clinic licens pharmacy, the Department of Co		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 34 of 45	PIC Initials

 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 another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a), 4187.2]

- The 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. California Correctional Health Care Services Health Care

  Department Operations Manual. [BPC 4187.2]

	Department Operations Manual. [BPC 4187.2]				
	<u>78</u> .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. <u>California Correctional Health Care Services Health Care Department Operations Manual.</u> [BPC 4187.1(b), 4187.2]				
Yes No N/A					
	78.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record-keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]				
	<u>78</u> .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)]				
	$\underline{78}$ .7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]				
	$\underline{78}$ .8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]				
	$\underline{78}$ .9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]				
	<u>7</u> 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)]				
	O 44 The ADDC tease and Commission and commission and the second tease of the second tease.				
	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	A		
	78.1≥1 The policies and procedures the correctional clinic was developed and Therapeutics Committee references	ed and approved by the sta	tewide Correctional Pharmacy
	78.132 Prior to the issuance of the of the policies and procedures was servicing the institution, the pharm and Rehabilitation's Central Fill Phasupervising dentist, chief nurse exercises	signed by the correctional facist-in-charge for the Calif rmacy, and the correctiona	facility pharmacist-in-charge fornia Department of Correction Il clinic's chief medical executive,
Yes No N/A	<u>7</u> 8.14 <u>3</u> The chief executive officer is pharmacy services. [BPC 4187.2(b)(		rderly and lawful provision of
	78.154 The pharmacist-in-charge of procedures developed and approve Committee referenced in section 50 Services California Correctional Head Department Operations Manual in medical executive, the supervising of	ed by the statewide Correct 042.2 of the Penal Code and 11th Care Services Policies a conjunction with the chief o	ional Pharmacy and Therapeutics d the <del>statewide Inmate Medical</del> <del>nd Procedures</del> <u>Health Care</u> executive officer, the chief
	<u>7</u> 8.165 The licensed correctional clir chief executive officer on a form fu		
	<u>7</u> 8.1 <u>76</u> Schedule II, III, IV or V contro the licensed correctional clinic lawf defined in section 4019, a valid pres and Professions Code, or pursuant to Inmate Medical Services Policies an Health Care Department Operation	ully authorized to administo scription consistent with ch to an approved protocol as <del>d Procedures <u>California Co</u></del>	er pursuant to a chart order, as apter 9 division 2 of the Business identified within the <del>statewide</del> rrectional Health Care Services
	<u>78.187</u> The ADDS located in a license Correctional Pharmacy and Therape statewide Inmate Medical Services Department Operations Manual Peaccountability, security, patient corpurity of drugs. [BPC 4187.5(a)]	eutics Committee's policies <u>California Correctional Hea</u> <del>licies and Procedures</del> to en	and procedures and the <a href="https://link.nih.google-color: blue;">https://link.nih.google-color: blue;</a> and the <a href="https://link.nih.google-color: blue;">https://link.nih.google-color: blue;</a> and the <a href="https://link.nih.google-color: blue;">https://link.nih.google-color: blue;</a> blue; and
	$\underline{\underline{78.198}}$ All policies and procedures a the location where the $\frac{\text{automated}}{\text{automated}}$		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 36 of 45	PIC Initials

		CTIVE ACTION OR ACTION	PLAN AND COMPLETION DAT	V DATE	
s No N/A		PHARMACIST RESPONSI	BILITIES		
	<u>7</u> 8. <del>20</del> 19	<u>9</u> A correctional facility pha	rmacist inspects the clinic at	least quarterly. [BPC 4187.2(c)]	
□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	author patien pharm review may casystem prescriadminithe stace Care Scan authors	rization by a pharmacist aft t profile for potential contract is closed, Where adminated the prescription and if, ause patient harm, the medical services Health Care Depart acy when it reopens. [BPC acy when it reopens.	nistration of the drug is neces in the prescriber's profession dication may be removed from furnished to the patient underwise unavailable, a medical patient pursuant to an appropries Policies and Procedure ment Operations Manual. An Seystem is documented and 4187.5(b)]	ed the prescription and the g reactions. If the correctional sary before a pharmacist has al judgment, a delay in therapy of the automated drug delivery der the direction of the tion may be removed and yed protocol as identified within a Correctional Health y removal of the medication from	
	inspec <del>autom</del>	tion of the drugs in the <del>aut</del> ated drug delivery system	<del>omated drug delivery system</del>	<u>ADDS</u> , an inspection of the s, and a review of all transaction	
		f Last Review:			
	CORRE	ECTIVE ACTION OR ACTION	PLAN AND COMPLETION DAT	E	
No N//	<b>4</b> <u>7</u> 8. <del>23</del> 22 license		the Business and Professions	patient by a health professional s Code who is lawfully authorized	
	17M-1	<b>12</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 37 of 45	PIC Initials	

	78.2423 The review of the drugs conta ADDS shall be the responsibility of the	•	
	$\frac{78.25}{24}$ The ADDS is operated by a lice are considered owned by the licensed ADDS. [BPC 4187.5(f)]	-	
	78.2625 Drugs from the ADDS in the costock the ADDS, or by a person lawful 4187.5(g)]		
	CORRECTIVE ACTION OR ACTION PLAN	N AND COMPLETION DATE	
Yes No N/A	E. RECORD KEEPING REQUIREMI	ENTS	
	78.2726 All records of manufacture an dangerous drugs or dangerous device inspection by authorized officer of the date of making. A current inventory is	s, at all times during business he e law and <del>is are</del> preserved for at	ours, are open for t least three years from the
	CORRECTIVE ACTION OR ACTION PLAN	N AND COMPLETION DATE	
	SECTION 98:  DRUG ROOM: AUDS used for dis (Hospital Pharmacy is closed and PURSUANT TO BPC 4056 (DRUG HOSPITAL PHARMACY: AUDS US	<del>l no pharmacist is available)</del>	FOR DISPENSING
	Please Note: Hospital pharmacies an used for administration. This section	addresses additional requirem	ents for hospital
	pharmacies and drug rooms operating	ng an ADDS uses for dispensing.	<u>.</u>
Yes No N/A	A. GENERAL REQUIREMENTS		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>2</u> 3)	Page 38 of 45	PIC Initials

	adm hos dete imm loca pati mea qua shal	ninistra pital, to ermine nediate ited ou ent wit ans of t ntity di Il not e	censed drug room does not employ a full-time pharmacist and the AUDS is used for tion and dispensation by a physician to persons registered as inpatients of the emergency cases under treatment in the hospital, or to outpatients if the physician is that it is in the best interest of the patient that a particular drug regimen be ely commenced or continued, and the physician reasonably believes that a pharmacy tside the hospital is not available and accessible at the time of dispensation to the thin 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by the method of transportation the patient states they he/she intend to use. The ispensed is limited to the amount necessary to maintain uninterrupted therapy, but exceed a 72-hour supply. [BPC 4056(a), (f)]
	incl	uding a	controlled substance, from the AUDS to an emergency room patient, the following apply [BPC 4068(a)]:
		<u>8.2.1</u>	when t The hospital pharmacy is closed and there is no pharmacist available in the hospital.
		<u>8.2.2</u>	The drugs is acquired by the hospital pharmacy.
		<u>8.2.3</u>	The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
		<u>8.2.4</u>	The hospital pharmacy retains the dispensing information <u>and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing</u>
	□	<u>8.2.5</u>	information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.  The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patients.
		8.2.6	The quantity dispensed is limited to the amount necessary to maintain
	<del>-</del>		uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. <del>[BPC 4068(a)(1-6)]</del>
		<u>8.2.7</u>	The prescriber ensures that the label on the drug contains all the information required by BPC section 4076.
Yes No N/A	١		
	8.3		erating pharmacy has obtained a license from the Board to operate the AUDS that is
		<u>d for ac</u> 7.2(i)]	dministration and dispensing which includes the address of the AUDS location. [BPC
Yes No N/4			
	_		prescriber ensures the label on the drug contains all the information required by BPC CCR 1707.5.

Page 39 of 45

PIC Initials \_\_\_\_\_

	eral warning labels prohibiting transfer of controlled substances is on the ontainer. [21 CFR 290.5]
ease-of-openi	scription drug is dispensed in a new and child-resistant container, or senior-adulting tested container, or in a non-complying package only pursuant to the request ber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
III or IV contro reasonably po	epital pharmacy or drug room reports the dispensing information of a Schedule II, colled substance to the Dept of Justice pursuant to HSC 11165 as soon as essible, but not more than seven days after the date a controlled substance is PC 4068(a)(4), HSC 11165(d)]
9.78.8 Patient	package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
9.8 <u>8.9</u> The hos information re from a drug ro	epital has written policies and procedures to ensure each patient receives egarding each drug given at the time of discharge or dispensed from a prescriber boom, including the use and storage of each drug, the precautions and relevant I the importance of compliance with directions. [BPC 4074(e)]
	ing pharmacy has obtained a license from the Board to operate the AUDS that is
<del>used for admi</del> <del>4427.2(i)]</del>	nistration and dispensing which includes the address of the AUDS location. [BPG
	on guides are provided on required medications. [21 CFR 208.1]  warning information is in conformance with 21 CFR 201.57(c).
	r an opioid prescription drug is dispensed to a patient for outpatient use, the practitioner dispensing the drug prominently displays on the label or container, by
means of a fla	ng or other notification mechanism attached to the container, a notice that states,
<u>"Caution: Opi</u>	oid. Risk of overdose and addiction." [ BPC 4076.7]
CORRECTIVE A	ACTION OR ACTION PLAN AND COMPLETION DATE
	AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY
	O PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH ACILITY, OR OTHER CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED
	CILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR.

**17M-112** (Rev. 1<del>2</del>/<del>18</del>2<u>23</u>)

Page 40 of 45

## A. GENERAL REQUIREMENTS

Yes No N/A	
<u> </u>	DDS is
done in accordance with law and is the responsibility of the pharmacy. A pharmacist con	<u>iducts</u>
the review on a monthly basis, which includes a physical inspection of the drugs in the A	DDS, an
inspection of the ADDS for cleanliness, and a review of all transaction records in order to	verify
the security and accountability of the ADDS. [BPC 4427.65(c)(7)]	
Date of Last Review:	
CORRECTIVE ACTION OR ACTION RIANI AND COMPLETION DATE	
CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE	
B. PHARMACIST RESPONSIBILITIES:	
Yes No N/A	
9.2 The stocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable	
pockets, cards, drawers, similar technology, or unit of use or single dose containers, as d	<u>efined</u>
by the United States Pharmacopoeia, the stocking system may be done outside of the fa	<u>cility</u>
and be delivered to the facility, if all the following conditions are met: [BPC 4427.65(c)(6	<u>)]</u>
☐ 9.2.1 The task of placing drugs into the removable pockets, cards, drawers, or unit	of use
or single dose containers is performed by a pharmacist, or by an intern pharn	<u>nacist</u>
or a pharmacy technician working under the direct supervision of a pharmaci	
9.2.2 The removable pockets, cards, drawers, or unit of use or single dose contained	
transported between the pharmacy and the facility in a secure tamper-evider	
	<u>1L</u>
container.	
9.2.3 The facility, in conjunction with the pharmacy, has developed policies and	
procedures to ensure that the removable pockets, cards, drawers, or unit of the	<u>use or</u>
single dose containers are properly placed into the ADDS.	
9.3 The pharmacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures	<u>the</u>
following: [CCR 1715.65(h)]	
9.3.1 All controlled substances added to an ADDS are accounted for.	
$\square$ 9.3.2 Access to the ADDS is limited to authorized facility personnel.	
□ 9.3.3 An ongoing evaluation of discrepancies of unusual access associated with cor	ntrolled
9.3.3 An ongoing evaluation of discrepancies or unusual access associated with cor	<u>itrolled</u>

	9.3.4 Confirmed losses of controlled substances are reported to the board.
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	C. <u>DEVICE REQUIREMENTS:</u>
es No N/A	9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel
	authorized by law to administer drugs. [BPC 4427.65(c)(2)]
	When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [BPC 4427.65(c)(4)]:
es No N/A	
<u> </u>	9.5 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(4)(A)]
	9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC 4427.65(c)(4)(B)]
	9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the ADDS pursuant to the order of the prescriber for emergency or immediate administration to the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist. [BPC 4427.65(c)(4)(C)]
	When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:
	9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]
	9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(5)(B)]

Page 42 of 45

PIC Initials \_\_\_\_\_

	9.10 The pharmacy providing state ADDS. [BPC 4427.65(c)(5)(	services to the facility controls the ac C)]	ccess to the drugs stored in
	the ADDS is limited only to dru and that are specific to the par	iews the prescriber's order, access bugs ordered by the prescriber and restient. When the prescriber's order runnel has access to the drug ordered c)(5)(F)]	viewed by the pharmacist equires a dosage variation of
	patient specific in their design	personnel to have access to multiple, shall be allowed if the ADDS has elethe drugs delivered to the patient ar	ectronic and mechanical
	CORRECTIVE ACTION OR ACTIO	ON PLAN AND COMPLETION DATE	
	D. RECORD KEEPING REQ	UIREMENTS	
Yes No N/A	9.13 Transaction information s inspection by individuals autho	shall be made readily available in a worized by law and are maintained in	
	three years. [BPC 4427.65(c)(1	ON PLAN AND COMPLETION DATE	
Yes No N/A	E. <u>POLICIES AND PROCED</u>	DURES	
	9.14 The pharmacy operating	the AUDS shall develop and implemess pertaining to the ADDS. [BPC 4427	-
	procedures to ensure safety, a maintenance of the quality, po	macy has developed and implemente accuracy, accountability, security, par otency, and purity of stored drugs. T I limits to access to equipment and d	tient confidentiality, and he policies and procedures
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 2 <u>23</u> )	Page 43 of 45	PIC Initials

CERTIFICATION ACKNOWLEDGMENT  PHARMACIST-IN-CHARGE CERTIFICATION:  I, (please print)	3.10 / til policies and proc	edures are maintained at the pharmacy operating the ADDS and the
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 responses are subject to verification by the Board of Pharmacy. I further state under pend of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature	location where the ADDS	is being used. [BPC 4427.5(c)(3)(B)]
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 responses are subject to verification by the Board of Pharmacy. I further state under pend of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature	CORRECTIVE ACTION OR	ACTION PLAN AND COMPLETION DATE
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 responses are subject to verification by the Board of Pharmacy. I further state under pend of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature		
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 tha responses are subject to verification by the Board of Pharmacy. I further state under pena of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature		
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 responses are subject to verification by the Board of Pharmacy. I further state under pend of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature		
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 responses are subject to verification by the Board of Pharmacy. I further state under penal of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature		
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 responses are subject to verification by the Board of Pharmacy. I further state under pend of perjury of the laws of the State of California that the information that I have provided it this self- assessment form is true and correct.  Signature  Date  (Pharmacist-in-Charge)  ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING THE OF-ADDS:  I, (please print)  [insert name and title], hereby cert under penalty of perjury under of-the laws of the State of California that I have full author without any limitations to provide this certification, that I am the Owner of the Pharmacy the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete. on the advicemental this completed self assessment. Further, I understand that failure to correct deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.		
ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING THE OF ADDS:  I, (please print) [insert name and title], hereby cert under penalty of perjury under of the laws of the State of California that I have full author without any limitations to provide this certification, that I am the Owner of the Pharmacy the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete. and reviewed this completed self-assessment. Further, I understand that failure to correct deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.	completed the self-asses pharmacist-in-charge. Ar responses are subject to of perjury of the laws of	sment of this automated drug delivery system of which I am the ny deficiency identified herein will be corrected. I understand that verification by the Board of Pharmacy. I further state under penal the State of California that the information that I have provided in
ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR HOSPITAL ADMINISTRATOR OPERATING THE OF ADDS:  I, (please print) [insert name and title], hereby cert under penalty of perjury under of the laws of the State of California that I have full author without any limitations to provide this certification, that I am the Owner of the Pharmacy the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete. and reviewed this completed self-assessment. Further, I understand that failure to correct deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.	Signature	Date
I, (please print) [insert name and title], hereby cert under penalty of perjury under efthe laws of the State of California that I have full author without any limitations to provide this certification, that I am the Owner of the Pharmacy the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete. earner eviewed this completed self-assessment. Further, I understand that failure to correct deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.	(Pharmacist-	in-Charge)
without any limitations to provide this certification, that I am the Owner of the Pharmacy the Hospital Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein is true, correct and complete. Fee and reviewed this completed self-assessment. Further, I understand that failure to correct deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.	ACKNOWLEDGMENT BY	OWNER OF THE PHARMACY OR HOSPITAL ADMINISTRATOR
deficiency identified in this self-assessment could result in the revocation of the automate drug delivery system's license issued by the California State Board of Pharmacy.	<i>OPERATING THE <del>OF</del></i> ADD	S:
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all factors.	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorial provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete.
Signature	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the second control of t	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorise provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. reacted self-assessment-Further, I understand that failure to correct and self-assessment could result in the revocation of the automated
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the Hospital Administrate acknowledge that all fact and reviewed this completed in the Hospital Administrate acknowledge that all fact and reviewed this completed in the Hospital Administrate acknowledge that all fact and reviewed this complete acknowledge in the Hospital Administration and the Hospita	[insert name and title], hereby certifunder of the laws of the State of California that I have full authority provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. reserved self-assessment-Further, I understand that failure to correct and self-assessment could result in the revocation of the automater.
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the drug delivery system's lice.	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorical provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. Feet assessment—Further, I understand that failure to correct his self-assessment could result in the revocation of the automate tense issued by the California State Board of Pharmacy.
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the drug delivery system's lice.	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorical provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. Feet assessment—Further, I understand that failure to correct his self-assessment could result in the revocation of the automate tense issued by the California State Board of Pharmacy.
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the drug delivery system's lice.	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorical provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. The state of the self-assessment. Further, I understand that failure to correct his self-assessment could result in the revocation of the automate sense issued by the California State Board of Pharmacy.
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the drug delivery system's lice.	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorical provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. The state of the self-assessment. Further, I understand that failure to correct his self-assessment could result in the revocation of the automate sense issued by the California State Board of Pharmacy.
	I, (please print) under penalty of perjury without any limitations to the Hospital Administrate acknowledge that all fact and reviewed this completed deficiency identified in the drug delivery system's lice.	[insert name and title], hereby certifunder of the laws of the State of California that I have full authorical provide this certification, that I am the Owner of the Pharmacy of Operating the ADDS and that I have reviewed this form, and its and information stated herein is true, correct and complete. The state of the self-assessment. Further, I understand that failure to correct his self-assessment could result in the revocation of the automate sense issued by the California State Board of Pharmacy.

Page 44 of 45

PIC Initials \_\_\_\_\_

### **CERTIFICATION OF COMPLETED ACTION PLAN**

PHARMACIST-IN-CHARGE CERTIFICA	TION:
corrected the deficiencies identified system of which I am the pharmacist verification by the Board of Pharmac	, RPH # hereby certify that I have in the self-assessment of this automated drug delivery r-in-charge. I understand that all responses are subject to by. I further state under penalty of perjury of the laws of mation that I have provided in this self- assessment form
Signature (Pharmacist-in-Charge)	Date
ACKNOWLEDGMENT BY <i>OF THE PHA</i> <del>QE</del> ADDS:	ARMACY OR HOSPITAL ADMINISTRATOR OPERATING THI
under penalty of perjury <u>under <del>of</del></u> the without any limitations to provide th the Hospital Administrator Operating acknowledge that all facts and inforr	[insert name and title], hereby certify e laws of the State of California that I have full authority, is certification, that I am the Owner of the Pharmacy or a the ADDS and that I have reviewed this form, and mation stated herein is true, correct and complete. read essment. Further, I understand that failure to correct any
deficiency identified in this self-asses	ssment could result in the revocation of the automated by the California State Board of Pharmacy.
Signature	Date

# **Attachment 4**

February 21, 2023

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Email: PharmacyRulemaking@dca.ca.gov

Members of the Board,

California Correctional Health Care Services (CCHCS) appreciates the opportunity to provide comment in response to the proposed modified text for California Code of Regulations §1715.1 Self-Assessment of an Automated Drug Delivery System by the Pharmacist-In-Charge. CCHCS operates approximately 39 licensed Correctional Pharmacies, 320 licensed Correctional Clinics and 480 Automated Drug Dispensing Systems (ADDS) across 33 Institutions. Therefore, the CCHCS Correctional Pharmacies average 13 automated drug dispensing systems per pharmacy.



California Correctional Health Care Services (CCHCS) provides medical and pharmacy services across all 33 institutions. All 480 Automated Drug Dispensed Systems are made by the same manufacturer, controlled by the same software system on a single server and function under the same set of policies and procedures within in the CCHCS Health Care Department Operations Manual. Each of the 33 institutions has a series of licensed correctional clinics and may have inpatient beds licensed by The California Department of Public Health, all located at one physical address and over seen by one Chief Executive Officer. Therefore, the ownership and operation of each institution falls under a single entity as does an inpatient hospital.

Currently, CCHCS licensed correctional pharmacies are completing a separate paper ADDS self-assessment for each of the ADDS attached to the pharmacy license which therefore requires duplication of the same information across many individual paper self-assessments.

In consideration of: single entity ownership and oversight, the average number of ADDS at each institution, an organizational set of policies and procedures meeting federal and state legal requirements, the number of self-assessments that each licensed correctional pharmacy would be required to physically complete with identical information, CCHCS is requesting that the following paragraph be added to the proposed modified text for California Code of Regulations §1715.1 Self-Assessment of an Automated Drug Delivery System by the Pharmacist-In-Charge:

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

. . .

- (g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliance with federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:
- (1) The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server;
- (2) The same policies and procedures required by Section 4427.2 of BPC are used;
  (3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment; and
- (4) Each single consolidated self-assessment is limited to ADDS devices which are located at a single institution and under a single Chief Executive Officer



In an effort to provide the ability to list all of the ADDS licenses incorporated into the single self-assessment form, CCHCS respectfully proposes a corresponding change to the self-assessment form. An image of the proposed change follows on the next page and would affect page 2 and page 3 of the self-assessment form. CCHCS has also attached the proposed self-assessment form changes as a Microsoft Word document attached entitled, "CCHCS Proposed 1715 1 sa.docx".

than the pharm	асу:	ose Great

No N/A	V2
	This is a consolidated Automated drug delivery system self-assessment for AUDS operated by a licensed
	correctional pharmacy inclusive of the following ADDS Licenses [CCR 1751.1(g)]:

ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
ADDS License #:	ADDS Expiration Date:
17M-112 (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 2 of 44 PIC Initials



Respectfully,

Grey Doe 4E4BC29F9620417... Greg Doe, Pharm.D.

Statewide Chief of Pharmacy Services

California Correctional Health Care Service

Greg.Doe@cdcr.ca.gov

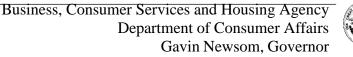
Cell: (916)658-3823



## 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





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

## **AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT**

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

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

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

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

Pharmacy Name:		
Address:		
City:		Zip Code:
Phone:	Fax number:	
Website:		
Pharmacy License #:	Expiration	Date:
DEA Registration #:	DEA Expira	ation Date:
DEA Inventory Date:	_ Last <u>C2</u> <u>CS</u> Inventory Reconciliation	on Date (CCR 1715.65(c)):
Pharmacy Hours: M-F:	Saturday	Sunday
ADDS License #:	ADDS Expiration	Date:
ADDS Address:		
<b>17M-112</b> (Rev. <del>12/18</del> 1/22)	Page 1 of 44	PIC Initials

City:	Zip Code:	
	Saturday Sunday	
Please explain if the ADDS hours a	re different than the pharmacy:	
This is a consolidated Automated	drug delivery system self-assessment for AUDS operated by	
<u>correctional pharmacy inclusive o</u>	f the following ADDS Licenses [CCR 1751.1(g)]:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #:	ADDS Expiration Date:	
ADDS License #.	ADDS Evniration Date:	

	ADDS License #:	ADDS Expiration Date:
	ADDS License #:	ADDS Expiration Date:
	ADDS License #:	ADDS Expiration Date:
	ADDS License #:	ADDS Expiration Date:
	THE STATE OF THE S	- TO STATE OF THE
	Reason for completing self-assessment:	
	Performing self-assessment before July 1 of e	very odd-numbered year. [BPC 4427.7, CCR
	Completing a self-assessment within 30 days 4427.7, CCR 1715.1(b)(1)]	when a new ADDS license was issued. [BPC
	☐ Completing a self-assessment within 30 days	when there was a change in PIC. [BPC
	4427.7, CCR 1715.1(b)(2)]	
	Completing a self-assessment within 30 days location of an ADDS to a new address. [BPC 4	
	FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1	L, 2 AND 3
	SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE An ADDS – "Automated drug delivery system," a or activities other than compounding or administration of drugs. An ADDS, shall collect, control to accurately track the movement of drugs into an and accountability. [BPC 4119.11(b)(1), 4017.3(a)	mechanical system that performs operations ration, relative to storage, dispensing, or rol, and maintain all transaction information and out of the system for security, accuracy,
Yes No N/A	IDENTIFY THE TYPE OF ADDS DEVICE USED	
	1.1. The pharmacy uses an APDS – "Automated P storage and dispensing of prescribed drugs direct authorization by a pharmacist. [BPC 4119.11(b)(2)]	ly to the patients pursuant to prior
	1.2 The pharmacy uses an AUDS – "Automated UI and retrieval of unit dose drugs for administration these functions. [BPC 4119.11(b)(3), 4017.3(b)]	· · · · · · · · · · · · · · · · · · ·
	1.3 The pharmacy uses an AUDS – "Automated UI and retrieval of unit dose drugs for administration drug room or hospital emergency room when the BPC 4068]	n and dispensing to patients by a physician in a
Yes No N/A	SECTION 2: LOCATION OF DEVICES	

Page 3 of 44

DocuSign Envelope ID: 913B4131-92B2-4414-8561-D430C04E6440

Page 4 of 44

PIC Initials

Yes No N/A	1 2.9 AUDS located in the emergen	ocy room onerated by a license	<b>d hospital pharmacy</b> , as defined
	in subdivisions (a) and (b) of sect		
	provide doses administered to p		
	a licensed acute psychiatric hosp		
	1250 of the Health and Safety Co		
	4068, 4427.2(i)]	•	
	2.9.1. The hospital pharm	acy is closed and there is no ph	narmacist available in the
	hospital.		
	2.9.2. The drug is acquired	d by the hospital pharmacy.	
	<u> </u>	rmation is recorded and provid	ed to the pharmacy when the
	pharmacy reopens.		
	☐ 2.9.4. The hospital pharm	acy retains the dispensing info	rmation and controlled
	substances dispensing inf	ormation is reported to the Dep	partment of Justice pursuant to
	section 11165 of the Heal	Ith and Safety Code.	
	2.9.5. The prescriber determined	ermines it is in the best interest	of the patient that a particular
	drug regimen be immedia	ately commenced or continued	and the prescriber reasonably
	believes a pharmacy locate	<u>ted outside the hospital is not a</u>	wailable and accessible at the
	time of dispensing to the	<u>patient.</u>	
	$\square$ 2.9.6. The quantity is limit	ted to an amount necessary to	<u>maintain uninterrupted</u>
	therapy, but shall not exc	<u>eed a 72-hour supply.</u>	
	Note: Licensure of AUDS operate	<u>ed under these provisions is rec</u>	<u>juired.</u>
	2.10 A facility licensed in CA with [BPC 4427.65(a)(1)]	n the statutory authority to pro	ovide pharmaceutical services.
	Type of Facility:		
	Statutory authority to provide ph	narmaceutical services (List code	e section):
		•	
	2.11 Jail, youth detention facility	, or other correctional facility	where drugs are administered
	within the facility under the aut	hority of the medical director.	[BPC 4427.3(b)(6), BPC
	4427.65(a)(2)]		
	<u>Type of Facility:</u>		
	Statutory authority for type of Fa	cility (List code section):	
	<u>Please</u> Note: An ADDS license is r		·
	licensed premises area of a phar		unting, packaging, and labeling
	of dangerous drugs and dangero	us devices. [BPC 4427.2(j)]	
	65.07.10.1.2	451176 500 411 71/056 05 400	_
	SECTION 3: GENERAL REQUIREN		<u> </u>
V N- N/A	(Answer N/A if licensure not requ	uired)	
Yes No N/A	3.1 The ADDS is installed, leased,	owned or operated in Californ	in and is licensed by the heard
	[BPC 4427.2(a), 4427.4(a)]	owned, or operated in Californ	and is need by the bodiu.
	[5: 6 7727.2(0], 4427.4(0]]		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 5 of 44	PIC Initials

Yes No N/	Yes No N/A  3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]			
	□□□ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]			
	3.4 The lice	ensed ADDS meets the	following conditions: [BPC 44	27.2(d)]
	☐ <u>3.4.1</u> ☐ <u>3.4.2</u>	The proposed locatio	nsistent with legal requireme n for installation of the ADDS ne ADDS is secure from access	
	<ul><li></li></ul>	The pharmacy's polic security measures an The pharmacy's polic	d monitoring of the inventory	the ADDS include appropriate to prevent theft and diversion. visions for reporting to the board by law.
Yes No N/	<u>A</u>			
	ADDS lice	•	cation(s). [BPC 4427.2(e)]	a completed application for the
	3.6 The ph	-	cation of an ADDS shall requi	re a new application for licensure.
	•	narmacy is aware a rep days. [BPC 4427.2(e)]	lacement of an ADDS shall red	quire notification to the board
	underlyin of the und	g pharmacy license is n		by operation of law if the Upon reissuance or reinstatement ADDS license is submitted to the
			older of an ADDS license will a ontinued. [BPC 4427.2(g)]	ndvise the board in writing within
		NDDS license <del>(s)</del> is <del>/were</del> g pharmacy license. [B		enewal date is the same as the
		NDDS is placed and ope pproved by the board.		ding, with a premises address, at a
	17M-112	(Rev. 1 <del>2</del> / <del>18</del> 22)	Page 6 of 44	PIC Initials

Yes No N/A	
A jo ao qı m	12 Prior to installation, the pharmacy holding the ADDS license and the location where the DDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, bintly developed and implemented written policies and procedures to ensure safety, accuracy, ccountability, security, patient confidentiality, and maintenance of the ADDS, as well as uality, potency, and purity of the drugs and devices. The policies and procedures are naintained at the location of the ADDS and at the pharmacy holding the ADDS license. BPC 4427.3(c)]
	13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license.
3.1 re	14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, egardless of the ADDS location, and is subject to inspection pursuant to BPC <u>section</u> 4008. BPC 4427.4(c)]
re fr	15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the esponsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed rom the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d). 119.11(a)(3)]
te Io	16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy echnician or intern pharmacist under the supervision of a pharmacist, except for an ADDS ocated in a health facility pursuant to HSC 1250, where the stocking and restocking of the DDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]
	17 Access to the ADDS is controlled and tracked using an identification or password system or iosensor. [BPC 4427.4(e)(2), 4427.65(c)(5)(D), HSC 1261.6(f)(4)]
ac	18 The ADDS makes a complete and accurate record of all transactions including all users ccessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), PC 4427.65(c)(5)(D), BPC 4119.11(f), HSC 1261.6(f)(5)]
lo a <sub>l</sub> re	19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS ocation, stored for no longer than 48 hours in a secured room within the ADDS location pproved by the board under section 4427.3 of the Business and Professions Code, and upon etrieval of the dangerous drugs and dangerous devices from the secured storage, is an eventory taken to detect any losses or overages? [BPC 4427.4(f)]
pı pı	20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license rovides training on the operation and use of the ADDS to the pharmacy personnel and to ersonnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). BPC 4427.5]

Page 7 of 44

Yes No N/A  3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed
pharmacy holding the ADDS license and separate from other pharmacy records.  [BPC 4427.7(b), BPC 4427.7(b), BPC 4119.11(j)]
3.22 The record of quality assurance review, as provided in California Code of Regulation section  1711(e), is immediately retrievable in the pharmacy for at least one year from the date the record was created. [CCR 1711(f)]
3.23 The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of
annual renewal of the pharmacy's license. [CCR 1711(f)]
3.24 The PIC of EACH ADDS completes a self-assessment of the pharmacy's compliance with federal and state pharmacy law and is performed [CCR 1715.1(a), (b)]:  Before July 1 of every odd-numbered year.
<ul> <li>Within 30 days whenever a new ADDS licensed has been issued.</li> <li>Within 30 days when there is a change in PIC.</li> </ul>
When there is a change in the licensed location of an ADDS to a new address.
using the components of Form 17M-112 (Rev 1/22) entitled "Automated Drug Delivery System Self-Assessment." [CCR 1715.1(c)]
3.26 The PIC responds "yes", "no", or "not applicable" about whether the ADDS is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting. [CCR 1715.1(c)(2)]
3.27 For each "no" response, the PIC provides a written corrective action or action plan to come into compliance with the law. [CCR 1715.1(c)(3)]
3.28 The PIC initialed each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form.  [CCR 1715.1(c)(4)]
3.29 The PIC has certified on the last page of the self-assessment that they are the PIC, has certified a timeframe within which any deficiency identified within the self-assessment will be corrected, and has acknowledged all responses are subject to verification by the Board of Pharmacy. The certification is made under penalty of perjury of the laws of the State of California and the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form. [CCR 1715.1(c)(5)]

Page 8 of 44

Yes No N/	<u>A</u>		
	= 3.30 The ADDS owner has certifie	d the final page of the self-asses	ssment that they have read and
	reviewed the completed self-ass		
	deficiency identified in the self-a	ssessment could result in the re	vocation of the ADDS license
	issued by the Board. The certification		-
	of California with an original han		•
	Code Section 1633.2(h) on the se		-
	Code Section 1033.2(II) on the 30	211 433C33111C11C1011111. [CCIX 1713.	<u> </u>
	3.31 Each self-assessment is com	nleted in its entirety and kent or	n file in the underlying
<u></u>	pharmacy for three (3) years after		<u> </u>
	is readily available for review du	ring any inspection by the Board	<u>. [CCR 1713.1(d)]</u>
	2.22 Any identified area of nanco	mpliance shall be corrected as s	nacified in the colf accomment
<u></u>	3.32 Any identified area of nonco	inpliance shall be corrected as s	<u>pecined in the sen-assessment.</u>
	[CCR 1715.1(e)]		
<u> </u>	3.33 The PIC ensures the following	ng: [CCR 1715.65(h)]	
	☐ 3.33.1 All controlled substan	<u>ces added to an ADDS are accou</u>	<u>nted for.</u>
	☐ 3.33.2 Access to the ADDS is	<u>limited to authorized facility per</u>	<u>sonnel.</u>
	☐ 3.33.3 An ongoing evaluation	of discrepancies or unusual acc	ess associated with controlled
	substances is performed.		_
	□ 3.33.4 Confirmed losses of co	ontrolled substance are renorted	I to the hoard
	<u> </u>	THE SUBSCULIE ALC TEPOTICE	to the source.
	3.34 The original board-issued AD	IDS permit and current renewal	are nosted at the ADDS
	premise, where they may be clea		
	premise, where they may be clea	arry read by the public. [BFC 403	<u>oı</u>
	<b>CORRECTIVE ACTION OR ACTION</b>	PLAN AND COMPLETION DATE	
			<u> </u>
	CHECK OFF THE TYPE OF ADDS U	JSED BY THE PHARMACY AND C	OMPLETE THE FOLLOWING
	SECTION(S) AS IT APPLIES TO TH	E TYPE OF ADDS THE PHARMAC	CY IS USING.
	Please Note: The Pharmacist-in-	Charge of the pharmacy and th	e <u>pharmacy</u> owner of the
	ADDS shall sign the Certification	Acknowledgment on page <u>33</u>	18 after completing the
	assessment.		
	☐ SECTION 4: <b>–</b> APDS used t	to provide pharmacy service to c	covered entities and medical
	professionals contracted		
	☐ SECTION 5: —ADDS	The a core of the core;	
	<del>-</del>	the secured pharmacy area (or)	
	<u>▼ ArD3</u> aujaceIII to	the secured pharmacy area (OI)	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 9 of 44	PIC Initials
		1 490 2 01 44	

- <u>APDS</u> located in <u>a Medical Offices (or)</u>
- APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice (or)
- APDS located at a clinic pursuant to HSC 1204, HSC 1204.1, BPC 4180, or BPC <u>4190.</u>

□ SECT	TION $6$ : = ADDS in a health facility pursuant to HSC 1250 that complies with HSC
1261	1.6.
	<del>ION 7 — APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.</del>
☐ SECT	TION <u>\$7:</u> — ADDS operated by a correctional clinic <u>pursuant to BPC 4187.1,</u>
4427	<u>7.3(b)(6), or 4427.65(a)(2)</u> .
□ SECT	`ION <u>₽8:</u>
<u>•</u>	Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 when the
	hospital pharmacy is closed and no pharmacist is available.
2	<u>Drug Room:</u> AUDS used for dispensing pursuant to BPC 4056.
☐ <u>SEC</u> 1	<u> ION 9:</u>
<u>9</u>	AUDS through a facility licensed in California with statutory authority to provide
	pharmaceutical services (or)
9	AUDS through a jail, youth detention facility, or other correctional facility where
_	drugs are administered within the facility under the authority of the medical
	director pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).
	APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND
MEDICAL PI	ROFESSIONALS CONTRACTED WITH A COVERED ENTITY
A CEN	IFDAL DECLUDENTAINES
A. GEN Yes No N/A	IERAL REQUIREMENTS
TES IND IN/A	
providing pl by any othe covered ent	d Entity May Contract with Pharmacy to Provide Services. The operating pharmacy narmacy services to the patients of the covered entity, including, unless prohibited r law, patients enrolled in the Medi-Cal program, shall be under contract with the lity as described in BPC section 4126 to provide those pharmacy services through the APDS. [BPC 4119.11(a)(2)]
published b	s between the covered entities and the pharmacy shall comply with the guidelines y the Health Resources and Services Administration and are available for inspection ing normal business hours. [BPC 4126(a)]
	rchased and received pursuant to section 256b of Title 42 of the United States Code be segregated from the pharmacy's other drug stock by physical or electronic

means. [BPC 4126(b)]

Page 10 of

Yes No N/A	<u>1</u>			
	4.4 All records of acquisition and dispos separate from the pharmacy's other re	_	ll be readily retrievable in a form	
	4.5 The drugs shall be returned to the d be dispensed to patient of a covered edistributed because of a change in circl [BPC 4126(c)]	ntity pursuant to sectio	n 256b of Title 42 USC cannot be	
	4.6 A licensee that participates in a cont this section shall not have both a pharr	·		
	CORRECTIVE ACTION OR ACTION PLAN	AND COMPLETION DAT	TE	
Yes No N/A	B. UNDERLYING OPERATING PHA	RMACY		
	4.7 The operating pharmacy has obtained includes the address of the APDS locationsite. [BPC 4119.11(a)(1)]		-	
	4.8 A separate license was obtained for concurrent with the pharmacy license. APDS at an address for which the Board 4119.11(a)(8), 4107]	(Note: The Board may i	ssue a license for operation of an	
	4.9 A prelicensure inspection of the pro 30 days after Board receipt of the APDS			
	Date of Inspection:			
	4.10 The pharmacy will submit a new A current APDS is relocated. [BPC 4119.1 4.11 The pharmacy will notify the Board discontinuing an APDS. [BPC 4119.11(a	1(a)(9)] d within 30 days of repla		
	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)]			
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> <u>22</u> )	Page 11 of 44	PIC Initials	

Yes No N/	<u>A</u> 4.13 The pharmacy does not have r	more than 15 APDS licenses f	or one underlying operating	
	pharmacy under this section. [BPC		,	
	1	2		
	3	4		
	5	6		
	7	8		
	9	10		
	11	12		
	13	14		
	15			
	4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11), CCR 1713(f)]  4.15 The operating pharmacy of an APDS has completed an annual biennial Self-Assessment pursuant to CCR 1715.1 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]  Date of Last Self-Assessment:  Reason: □ Biennial; □ New ADDS; □ Change in PIC; □ Change in location of ADDS			
	4.16 The operating pharmacy has c	omplied with all recordkeepi	ng and quanty assurance	
	holding the APDS and separately fi			
	4.17 The pharmacy is aware that the pharmacy's drug inventory and the been dispensed by that pharmacy.	0 1 /	F O	
	4.1 <del>8</del> 6 The underlying operating pha	armacy is solely responsible f	or: [BPC 4119.11(a)(5), (6)]	
		PDS. [BPC 4119.11(a)(5)]		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 12 of 44	PIC Initials	

$\underline{\Box}$ 4.16.4 The training regarding the operation and use of the APDS for both the phand covered entity personnel using system. [BPC 4119.11(a)(6)]			
	CORRECTIVE ACTION OR ACTION	ON PLAN AND COMPLETION DATE	::
	C. PHARMACIST RESPON	SIBILITIES	
Yes No N/	4.1 <u>97</u> The operation of the API behalf of the operating pharm	OS is under the supervision of a lic nacy. [BPC 4119.11(a)(7)]. Note: The of the APDS and may supervise the	ne pharmacist need not be
	pockets, cards, drawers, similar	ns the stocking of the APDS or if the arms or if the stocking of the APDS or if the facility if the done outside of the facility if the facility is the facility if the facility if the facility is the facility is the facility is the facility if the facility is the facili	ngle dose containers are used,
	supervision of the pharma similar technology, or unit  4.2918.2 Transportation of unit of use or single dose of evident container. [BPC 42]		oveable pockets, cards, drawers, [BPC 4119.11(g)(1)] wers or similar technology <u>o</u> er and the facility are in a tamper-
		ies and procedures to ensure the gy, or unit of use or single dose could)	•
	of the drugs contained within	ucts a monthly review of the APDS, operation, maintenance, and cled as in order to verify the security a	anliness of the APDS, and a
	Date of Last Review:		
	4. <u>2220</u> The Pharmacist-in-char [CCR 1715.65(h)]	ge of the offsite ADDS/APDS has e	ensured the following:
	4.20.1 All controlled subs	tances added to the ADDS/APDS a	re accounted for;
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 13 of 44	PIC Initials

	<ul> <li>4.20.2 Access to ADDS/APDS is limited to authorized facility personnel;</li> <li>4.20.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and</li> <li>4.20.4 Confirmed losses of controlled substances are reported to the Board.</li> </ul>
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE:
	D. DEVICE REQUIREMENTS
Yes No N/	4.2 <u>31</u> 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)] 4.252 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]
	$4.2 \frac{63}{2}$ The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]
	4.2 <del>7</del> The APDS may dispense medications <b>DIRECTLY</b> to the patient if <b>all</b> the following are met: [BPC 4119.11(d)]
	4.2₹4.1 The pharmacy has developed, and implemented, and maintained written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) (d)(1)(F), CCR 1713(e)]
	<ul> <li>4.24.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.</li> <li>4.24.1.2 Determining=e and applying inclusion criteria regarding which drugs,=and devices are appropriate for placement in the APDS and for which</li> </ul>
	patients, including when consultation is needed.

Page 14 of 44

	4.24.1.4 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location, regarding maintenance and filling procedures for the APDS.
	4.24.1.5 Orienting patients on <u>the</u> 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.
	$\underline{\Box}$ <u>4.24.1.6</u> Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event <u>that</u> the APDS is disabled or malfunctions.
	Date of Last Policy Review:
	4.2¥4.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC
_	4119.11(d)(2) <u>, CCR 1713(d)(1)]</u>
<del>Yes No N/A</del> □	4.2 $\frac{74}{4}$ .3 The device-APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3), CCR 1713(d)(3)]
	4.274.4 The pharmacist has performed all clinical services as part of the dispensing process including, but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]
	$4.2$ $\pm 4.5$ Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]
	4.274.6 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)]
	4.274.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]
	4.274.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]
	7.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the
□□□ 4.2€	armacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]  35 The federal warning label prohibiting transfer of controlled substances is on the escription container. [21 CFR 290.5]

Page 15 of 44

Yes No N/A	
	4.2 <u>96</u> 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. <del>30</del> 27 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
	4. $\frac{3128}{2}$ The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
	4. <del>32</del> 29Medication guides are provided on required medications. [£21 CFR 208.1]}
	4.30 The pharmacy uses the APDS to deliver prescription medications to patients as provided: [CCR 1713(d)]
	☐ 4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the
	prescription medication to the patient.  4.30.2 The APDS has a means to identify each patient and only release the patient's
	prescription medications to the patient or patient's agent.  4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either inperson or via telephone, upon the request of a patient.
	4.30.4 Any incident involving the APDS where a complaint, deliver error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated
	by Business and Professions Code section 4125.
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/A	E. RECORD KEEPING REQUIREMENTS
	4.33 The operating pharmacy has complied with all recordkeeping and quality assurance
	requirements pursuant to BPC 4119.11 and those records shall be maintain within the
	pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]
	4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]
	4.3 $\frac{5}{1}$ Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22) Page 16 of 44 PIC Initials

	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
Yes No N//	F. POLICIES AND PROCEDURES
	$4.3\frac{62}{2}$ The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually [BPC 4119.11(d)(1), CCR 1713(e)]:
	<u>4.32.1</u> Maintaining the security of the APDS and dangerous drugs and devices within the APDS.
	4.32.2 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.
	4.32.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
	4.32.4 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
	4.32.5 Orienting patients on use of the APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
	4.32.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event if the APDS is disabled or malfunctions.
	Date of Last Policy Review:
	4.3 <u>84</u> -The pharmacy reports drug losses as required by law. [BPC 4104, <u>4427.2(d)(4)</u> 4105.5(c), CCR 1715.6, 21 CFR 1301.76]
	Last Reported Drug Loss:
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.

• Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

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

□ 5.2.1 A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to deliver of prescription medication to the patient.

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

□ 5.2.3 The pharmacy provides an immediate consultation with a pharmacist, either inperson or via telephone, upon the request of a patient.

17M-112 (Rev. 12/1822)

Page 18 of 44

PIC Initials

	<u>□</u> <u>5.2.4</u>	occurred shall be	lving the APDS where a complaint, delivery or reviewed as part of the pharmacy's quality iness and Professions Code section 4125.	
Yes No N/A	5.3 The pha pharmacy u	rmacy does not ha	ve more than 15 APDS licenses for one unde BPC 4427.6(k)] List of current APDS licenses _22.	:
	3		4	
	5		6	
	7		8	
	9		10	
	11		12	
	13		14	
	15			
	CORRECTIVI	E ACTION OR ACTIO	ON PLAN AND COMPLETION DATE	
B. PHAR Yes No N/A		PONSIBILITIES:		
	5.4 A pharm	orocess, including <u>.</u>	ne board performs all clinical services condu- but not limited to, drug utilization review ar	
	pharmacist	has reviewed the p	the APDS only upon authorization from the porescription and the patient's profile for potential drug reactions. [BPC 4427.6(e)]	•

Page 19 of 44

Yes No N/A	C. The phages sist shall consult wat:	anta fautha fiust tiusa an	مورين و مرور مورين و مراين و مراين		
	5.6 The pharmacist shall consult patidispensed from the APDS. All prescri		,		
	APDS for the first time are accompan				
	pharmacist. The consultation shall be	•			
	telecommunication link that has two	•	-		
	telecommunication link that has two	-way addio alid video cap	(abilities: [BPC 4427.0(1)]		
Yes No N/A					
	5.7 The <del>P</del> pharmacist-in-charge of the	e offsite ADDS/APDS has	ensured the following:		
	[CCR 1715.65(h)]				
	☐ <u>5.7.1</u> All controlled substances	added to the ADDS/APDS	are accounted for;		
	5.7.2 Access to ADDS/APDS is li	mited to authorized facili	ty personnel;		
	$\Box$ 5.7.3 An ongoing evaluation of $\Box$	discrepancies or unusual a	access associated with controlled		
	substance is performed; a	nd			
	□ 5.7.4 Confirmed losses of contr	olled substances are repo	orted to the Board.		
	<del></del>				
	5.8. The pharmacy operating the APE	S has completed an annu	ual Self-Assessment pursuant to		
	CCR 1715 evaluating the pharmacy's	compliance with pharma	cy law relating to the use of the		
	APDS. [BPC 4427.7(a)]				
	Date of Last Self Assessment:		<u> </u>		
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE				
_	C. DEVICE REQUIREMENTS:				
Yes No N/A	!				
	5.9 The stocking of the APDS is perfo	, ,	, ,		
	intern pharmacist under the supervis	1	1		
	facility pursuant to HSC 1250, where				
	performed in compliance with HSC 1	<del>261.6. [BPC 4427.4(e)(1)]</del>			
	5.10 Access to the APDS is controlled	and tracked using an ide	intification or password system or		
	<del>biosensor. [BPC 4427.4(e)(2)]</del>				
	5.11 The ADDS makes a complete an		S		
	accessing the system and all drugs ac	<del>lded to, or removed from</del>	<del>, the system. [BPC 4427.4(e)(3)]</del>		
	-5.12 Drugs and devices not immediat	,	•		
	location are stored for no longer than	<del>148 hours in a secured ro</del>	oom within the APDS location.		
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> <u>22</u> )	Page 20 of 44	PIC Initials		

	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. <u>448</u> 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. <u>459</u> 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. <u>46</u> 10 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]		
	5. <u>4711</u> 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. <u>48</u> 12 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]		
	5.4913 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. <del>20</del> 14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]		
	5.2415 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]		
	5.2216 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]		
	5.2317 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).		
	5.2418 Medication guides are provided on required medications. [21 CFR 208.1]		

Page 21 of 44

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 records. [BPC 4427.7(b)]  5.2619 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.]  5.2720 Any records maintained electronically must be maintained so that the pharmacis	
requirements pursuant to BPC 4427.6 and those records shall be maintain within the pholding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]  5.2619 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.  5.2720 Any records maintained electronically must be maintained so that the pharmacis	
holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]  5.2619 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.  5.2720 Any records maintained electronically must be maintained so that the pharmacis	
dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.  5.2720 Any records maintained electronically must be maintained so that the pharmacis	<del>armacy</del>
	11(a)(4)]
charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at a during which the licensed premises are open for business, be able to produce a hardcopelectronic copy of all records of acquisition and disposition or other drug or dispensing-records maintained electronically. [BPC 4105(d)(1)]	ll times by and
CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE	
E. POLICIES AND PROCEDURES Yes No N/A	
5.2821 The pharmacy has developed and implemented written policies and procedures verspect to all the following and the policies are maintained and reviewed annually: [BPC 4427.6(a) 4427.6(a) (6), CCR 1713(e)	
$\Box$ 5.21.1 Maintaining the security of the APDS and dangerous drug and devices wit APDS.	hin the
$\square$ 5.21.2 Determining= $\square$ and applying inclusion criteria regarding which drugs and,= are appropriate for placement in the APDS and for which patients.	devices
$\Box$ 5.21.3 Ensuring patients are aware that consultation with a pharmacist is available any prescription medication including those delivered via APDS.	
5.21.4 Describing assignment of responsibilities and training of pharmacy person and other personnel using the APDS at that location regarding maintenar filling procedures for the APDS.	
<ul> <li><u>5.21.5</u> Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure th</li> <li>17M-112 (Rev. 1²/1822)</li> <li>Page 22 of 44</li> <li>PIC Initials</li> </ul>	e use of

	the APDS does not interfere with the delivery of drugs and devices.		
<b>17M-112</b> (Re	ev. 1 <del>2</del> / <del>18</del> <u>22</u> )	Page 23 of 44	PIC Initials

		ivery of drugs and devices to pation the APDS in the event the APDS	. •
	Date of Last Policy Revie	ew:	
Yes No N/A		Irug losses as required by law. [BI	PC 4104, <u>4427.2(d)(4)</u> <del>4105.5(c)</del> ,
	Last Reported Drug Loss:		
	CORRECTIVE ACTION OR ACTIO	N PLAN AND COMPLETION DATE	
	SECTION 6: ADDS IN A HEALTH FACILITIES THAT COMPLIES WI	FACILITY PURSUANT TO HSC 129 TH HSC 1261.6	50 <del>– LONG TERM CARE</del>
	A. GENERAL REQUIREMEN	ITS	
	·	ACILITY" means a <u>ny</u> health facilit tion 1250 of the Health and Safet <del>1261.6(a)(2) </del> 1250]	•
		HARMACY SERVICES" means the Is to meet the needs of the patie	-
Yes No N/A			
	6.1 The facility and the pharma	cy has developed and implement	ed written policies and
		curacy, accountability, security, pell as quality, potency, and purity (161-6 (d)(1)	• • • • • • • • • • • • • • • • • • • •
	6. <u>≥1</u> The ADDS policies and proceeding equipment and drugs. [HSC 126	cedures define access to the ADD [51.6(d)(1)]	S and limits to access to
	•	dures are maintained at the phar	macy and the location where
	the ADDS is being used. [HSC 17	<del>261.6(d)(2), BPC 4427.3(c)]</del>	
	6.42 The pharmacy is responsible operation and maintenance of	ole for review of drugs contained the ADDS. [HSC 1261.6(h)]	within the ADDS and the
	CORRECTIVE ACTION OR ACTIO	N PLAN AND COMPLETION DATE	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 24 of 44	PIC Initials

v		ARMACIST RESPONSIBILITIES:
Yes No N/A	6. <u>53</u> The stopockets, can the stocking	cking of the ADDS is performed by a pharmacist_or_if the ADDS utilizes removable ds, drawers, similar technology, or unit of use or single dose containers—are—used, system may be done outside the facility and be delivered to the facility if the anditions are met: [HSC 1261.6(g)]
	use or a	3.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or or single dose containers is performed by a pharmacist, or by an intern pharmacist pharmacy technician under the direct supervision of a pharmacist. $3.1261.6(g)(1)$
	□ 6. <del>5</del> <u>·</u> are	.2 The removable pockets, cards, drawers, or unit of use or single dose containers transported between the pharmacy and the facility in a secure tamper-evident ainer. [HSC 1261.6(g)(2)]
	pro	.3 The facility, in conjunction with the pharmacy, has developed policies and edures to ensure that the removable pockets, cards, drawers, or unit of use or e dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]
Yes No N/	<u>'A</u>	
	<del></del>	ualized and specific access to the ADDS is limited to facility and contract personnel by law to administer drugs. [HSC 1261.6(c)]
	ADDS for a	macist reviews and approves all orders prior to a drug being removed from the lministration to a patient. The pharmacist reviews the prescriber's orders and the ofile for potential contraindications and adverse drug reactions. [HSC 1261.6(f)(2)]
	6.6 A Sched	lle II controlled substance for a patient in a licensed skilled nursing facility or
		ermediate care facility is dispensed only after the pharmacist has received:
	<u>pre</u> <u>han</u>	L An <b>orally transmitted</b> prescription for a Schedule II controlled substance from the criber and only after the pharmacist reduced the prescription to writing in ink in the dwriting of the pharmacist on a form developed by the pharmacy. The prescription to contain: [HSC 11167.5(a)]  6.6.1.1 The date the prescription was orally transmitted by the prescriber. 6.6.1.2 The name of the person for whom the prescription was authorized.
		6.6.1.3 The name and address of the licensed skilled nursing facility or licensed
		intermediate care facility in which the person is the patient.  6.6.1.4 The name and quantity of the controlled substance prescribed.  6.6.1.5 The directions for use, and the name, address, category of the

Page 25 of 44

		professional licensure, license number, and federal controlled substance
		registration number of the prescriber.
	□ 6.6.1.6	The prescription is endorsed by the pharmacist with the pharmacy's
		name, license number, and address.
	<u>6.6.2 Prior to</u>	o filling a prescription for a Schedule II controlled substance that has been
		y transmitted, the pharmacist has produced, signed, and dated a hard
	copy prescri	ption. The prescription must contain: [HSC 11167.5(a)]
	<u>□</u> <u>6.6.2.1</u>	The date the prescription was electronically transmitted by the
		prescriber;
	<u> </u>	The name of the person for whom the prescription was authorized;
	<u> </u>	· · · · · · · · · · · · · · · · · · ·
		intermediate care facility in which the person is the patient;
		The name and quantity of the controlled substance prescribed:
	☐ <u>6.6.2.5</u>	The directions for use, and the name, address, category of the
		professional licensure, license number, and federal controlled substance
		registration number of the prescriber.
	<u> </u>	The prescription is endorsed by the pharmacist with the pharmacy's
	□ 662 <b>7</b>	name, license number, and address.
	<u> </u>	The prescription contains the signature of the person who received the
		controlled substance for the licensed skilled nursing facility or licensed
		intermediate care facility.
П	6 6 3 An orig	inal Schedule II prescription is written on a form that complies with Health
=		ode section 11162.1. [HSC 11164(a)]
	arra sarety c	<u>oue section 11102.1. (1130 1110 1/4/)</u>
	6.6.4 An orig	ginal Schedule II prescription is written with the "11159.2 exemption" for
_		ly ill. [HSC 11159.2]
	6.6.5 In an e	mergency where failure to issue the prescription may result in loss of life
		uffering, a Schedule II controlled substance may be dispensed from a
		transmitted orally or electronically by a prescriber or written on a form
		ied in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]
		· · · · · · · · · · · · · · · · · · ·
	☐ <u>6.6.5.1</u>	The order contains all information required by subdivision (a) of Section
		<u>11164.</u>
	<u>□</u> <u>6.6.5.2</u>	If the order is written by the prescriber, the prescription is in ink, signed,
		and dated by the prescriber.
	<u> </u>	If the prescription is orally or electronically transmitted, it must be
		reduced to hard copy.

Page 26 of 44

form that meets the requirements of HSC 11162.1 by the seventh da	<u>¥</u>
following the transmission of the initial order.	
☐ 6.6.6 An electronic prescription (e-script) for controlled substances that is received	=
from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 131	<u>1]</u>
Yes No N/A	
6.87 The review of the drugs contained within the ADDS and the operation and maintenance 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 ver the security and accountability of the system. [HSC 1261.6(h)]	
Date of Last Review:	
☐☐☐ 6. <u>98</u> The <u>p</u> Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]	
<ul> <li>☐ 6.8.1 All controlled substances added to the ADDS are accounted for;</li> <li>☐ 6.8.2 Access to ADDS is limited to authorized facility personnel;</li> <li>☐ 6.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and</li> <li>☐ 6.8.4 Confirmed losses of controlled substances are reported to the Board.</li> </ul>	
6.149 The pharmacy operating the ADDS has completed an biennial Self-Assessment pursu to BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the 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	
ロロロ 6. <u>4410</u> The stocking and restocking of the ADDS is performed in compliance with section 12 of the Health and Safety Code. [BPC 4427.4(e)(1) <u>, HSC 1261(c), (g)</u> ]	61.6
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 de any losses or overages. [BPC 4427.4(f)]	<del>-</del> <del>tect</del>

Page 27 of 44

Yes No N/A	
	6. <u>43</u> 11 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]
	6. <u>1412</u> 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)]
Voc No N/A	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)]:
	6.4513 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. <u>1614</u> 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)]
	6.4715 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. $\frac{18}{16}$ Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]
	$6.\underline{1917}$ 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. <del>20</del> 18 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6(f)(3)]
	6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]

Page 28 of 44

	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),
Yes No N/A	H <del>SC 1261.6(f)(5)]</del> A
	6.2319 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)]
	6.2420 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)]
	6.2521 If the ADDS allows licensed personnel to have access to multiple drugs and are is not patient specific in itstheir design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. $\{[HSC 1261.6(f)(7)]\}$ .
	Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
	D
Yes No N//	D. RECORD KEEPING REQUIREMENTS
	6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed
	pharmacy holding the ADDS license and separate from the other pharmacy records.
	[BPC 4427.7(b)]
Yes No N/A	6.2722 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]
	6.23 Records of inspections completed by the pharmacist are kept for at least three years.  [HSC 1261.6(b), 22 CCR 70263(f)(3)]
	17M-112 (Rev. 1 <del>2</del> / <del>18</del> 22) Page 29 of 44 PIC Initials

	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE		
Yes No N/A	E. POLICIES AND PROCEDURES		
	6.2824 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. <del>29</del> 25 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]		
	6.3026 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)]		
	$6.\overline{3127}$ 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)]		
	6.3328 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//	_ <del>_</del>		

Page 30 of 44

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
<del>1204.1. [BPC 4427.3(b)(3)]</del>
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.
<del>[CCR 1715.65(a)]</del>
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:
<ul> <li>A physical count (not estimate) of all quantities of all federal Schedule II controlled</li> </ul>
<del>substances.</del>
<ul> <li>A review of all acquisition and disposition records of federal Schedule II controlled</li> </ul>
substances since that last inventory reconciliation report:
Date of last inventory
<ul> <li>A comparison of (1) and (2) to determine if there are any variances.</li> </ul>
<ul> <li>All records used to compile each inventory reconciliation report shall be maintained at</li> </ul>
clinic for 3 years in a readily retrievable form.

Page 31 of 44

• Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Yes No N//	
	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
	<del>3 years. [CCR 1715.65(e)]</del>
	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]
	<del>prescription container. [E1 of N E30.3]</del>
	7.14 Prescriptions are dispensed in a new and shild-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]
	When requested by the parenasen [15 656 1175(6), 16 61 (17 60.15), 66 (17 17)
	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
	<del>21 CFR 201.57(c).</del>
	7.17 Medication guides are provided on required medications. [21 CFR 208.1]
	7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous
	devices to patients of the clinic? [BPC 4427.6j)]
	7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
	List of current APDS licenses:
	1
	±
	2
	<u> </u>
	5. 6.
	<u></u>

	7. 8.	
	0 10	
	<del>910.</del>	
	<del>11.</del>	
	<del>13.                                    </del>	
	<del>15.</del>	
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION	I DATE
Yes No N//	<u>B. PHARMACIST RESPONSIBILITY</u> <u>/A</u>	
	7.20 The pharmacist performs the stocking of the ADDS. [I	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 p contraindications and adverse drug reactions. [BPC 4186]	
	7.22 The pharmacist shall conduct a review on a monthly	
	the drugs in the ADDS for cleanliness and a review of all t the security and accountability of the ADDS. [BPC 4186(d	•
	Date of Last Review:	
	7.23 The pharmacist licensed by the board performs all cli dispensing process, including, but not limited to, drug uti [BPC 4427.6(d)]	•
Yes No N//		
	7.24 Drugs are dispensed from the APDS after the pharma the patient's profile for potential contraindications and a	
	7.25 All prescribed drugs and devices dispensed to the passhall be accompanied by a consultation conducted by a telecommunication link with a two way audio and video.	harmacist licensed by the board via

Page 33 of 44

	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
Yes No N//	<u>C. POLICIES AND PROCEDURES</u>
	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)]
	<ul> <li>Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.</li> </ul>
	<ul> <li>Determining and applying inclusion criteria regarding which drugs and devices are</li> </ul>
	appropriate for placement in the APDS and for which patients.
	<ul> <li>Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.</li> </ul>
	<ul> <li>Describing assignments of responsibilities to, and training of, pharmacy personnel, and other</li> </ul>
	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.
	<ul> <li>Orienting participating patients on the use of the APDS, notifying patient when expected</li> </ul>
	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.
	<ul> <li>Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS</li> </ul>
	in the event the APDS is disabled or malfunctions.
	Date of Last Policy Review:
Yes No N//	• 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(I)]
	7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.  [BPC 4427.7(b)]
SECTION	87: ADDS OPERATED BY A CORRECTIONAL CLINIC
	A. GENERAL REQUIREMENTS
Yes No N/A	78.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]
	78.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Co $\pm$ de, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. $\pm$ [BPC 4187(a)].
Yes No N/A	<ul> <li>78.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a), 4187.2]</li> <li>The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.</li> <li>An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. California Correctional Health Care Services Health Care Department Operations Manual. [BPC 4187.2]</li> </ul>
	78.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified

within the statewide Inmate Medical Services Policies and Procedures. <u>California Correctional</u> <u>Health Care Services Health Care Department Operations Manual.</u> [BPC 4187.1(b), 4187.2]

Yes No N/A	78.5 Medications dispensed to patients that are kept on the patient's person for use shall me the labeling requirements of section 4076 and all record-keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]					
	78.6 The correctional clinic keeps record administered, transferred, and dispense maintained for a minimum of three year [BPC 4187.1(c)]	d. The records must be readily	available and			
	78.7 The correctional clinic has obtained	a license from the board. [BPC	24187.1(d)(1)]			
	78.8 A separate license was obtained for located and is not to be transferrable. [E		on where an APDS is			
	78.9 The correctional clinic's location an and building within the correctional inst	•	orrectional institution			
	78.10 The correctional clinic will notify t address on a form furnished by the boar	•	inge in the clinic's			
	8.11 The ADDS is secured from access an [BPC 4427.2(d)(2)]	d removal by unauthorized ind	ividuals.			
	CORRECTIVE ACTION OR ACTION PLAN	AND COMPLETION DATE				
	B. POLICIES AND PROCEDURES					
Yes No N/A	A <u>78</u> .1 <u>21</u> The policies and procedures to in the correctional clinic was developed an and Therapeutics Committee referenced	d approved by the statewide C	Correctional Pharmacy			
	78.132 Prior to the issuance of the correctional clinic license by the board, an acknowledgme 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 Correctio 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)]					
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 36 of 44	PIC Initials			

Yes No N/	<u>4</u> <u>7</u> 8.14 <u>3</u> The chief executive officer is	rosponsible for the safe of	orderly and lawful provision of
	pharmacy services. [BPC 4187.2(b)(2		orderry and lawrur provision of
	78.154 The pharmacist-in-charge of procedures developed and approve Committee referenced in section 50 Services California Correctional Head Department Operations Manual in Commedical executive, the supervising of	d by the statewide Correct 142.2 of the Penal Code ar 1th Care Services Policies Conjunction with the chief	ctional Pharmacy and Therapeutics and the <del>statewide Inmate Medical</del> and Procedures <u>Health Care</u> f executive officer, the chief
	<u>78</u> .1 <u>65</u> The licensed correctional clin chief executive officer on a form fur		
	78.1∓6 Schedule II, III, IV or V contro the licensed correctional clinic lawfu defined in section 4019, a valid pres and Professions Code, or pursuant t Inmate Medical Services Policies and Health Care Department Operations	ully authorized to adminis cription consistent with c o an approved protocol a <del>d Procedures</del> <u>California C</u>	ter pursuant to a chart order, as hapter 9 division 2 of the Business s identified within the <del>statewide</del> orrectional Health Care Services
	78.187 The ADDS located in a license Correctional Pharmacy and Therape statewide Inmate Medical Services Department Operations Manual Polaccountability, security, patient conpurity of drugs. [BPC 4187.5(a)]	utics Committee's policie <u>California Correctional He</u> <del>icies and Procedures</del> to e	s and procedures and the alth Care Services Health Care nsure safety, accuracy,
	78.198 All policies and procedures are the location where the automated of		• •
	CORRECTIVE ACTION OR ACTION PL	AN AND COMPLETION DA	TE
Yes No N/	C. PHARMACIST RESPONSIBIL	ITIES	
	78.2019 A correctional facility pharm	nacist inspects the clinic a	t least quarterly. [BPC 4187.2(c)]
	78.2120 Drugs removed from the au authorization by a pharmacist after patient profile for potential contrain	the pharmacist has review	wed the prescription and the
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 37 of 44	PIC Initials

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

Yes No N/A	<u>//A</u>	•	
	7 <u>8.22</u> 1 The review is conducted on a moning inspection of the drugs in the automated of automated drug delivery system ADDS made records in order to verify the security and a	I <del>rug delivery system-</del> ADDS, a chine for cleanliness, and a r	n inspection of the eview of all transaction
	Date of Last Review:		
	CORRECTIVE ACTION OR ACTION PLAN AN	D COMPLETION DATE	
Yes No N/	D. DEVICE REQUIREMENT		
	7 <u>8.2322</u> Drugs removed from the ADDS <del>is </del> a licensed pursuant to division 2 of the Busin to perform the task. [BPC 4187.5(c)]	<del></del> ;	· · · · · · · · · · · · · · · · · · ·
	7 <u>8.2423</u> The review of the drugs contained ADDS shall be the responsibility of the corr	•	
	7 <u>8-2524</u> The ADDS is operated by a license are considered owned by the licensed corr ADDS. [BPC 4187.5(f)]	-	•
	7 <u>8.2625</u> Drugs from the ADDS in the correct stock the ADDS, or by a person lawfully au 4187.5(g)]	•	•
	CORRECTIVE ACTION OR ACTION PLAN AN	D COMPLETION DATE	
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22) P	age 38 of 44	PIC Initials

Yes No N/	E. RECORD KEEPING REQUA	UIREMENTS	
	dangerous drugs or dangerous inspection by authorized office	devices, at all times during buer of the law and is are preserved.	eceipt, shipment, or disposition of usiness hours, are open for yed for at least three years from the orrectional clinic. [BPC 4081(a)]
	CORRECTIVE ACTION OR ACTIO	ON PLAN AND COMPLETION DA	ATE
	(Hospital Pharmacy is clo PURSUANT TO BPC 4056 HOSPITAL PHARMACY: A	AUDS USED FOR DISPENSING PU cies and drug rooms must also section addresses additional r	o complete Section 6 for ADDS equirements for hospital
Yes No N/A	A. GENERAL REQUIREMENT	S	
	89.1 The licensed drug room do administration and dispensation hospital, to emergency cases undetermines that it is in the best immediately commenced or collocated outside the hospital is patient within 30 minutes of the means of the method of transport	on by a physician to persons render treatment in the hospital tinterest of the patient that a patient and the physician render available and accessible and hospital pharmaceutical serportation the patient states the other amount necessary to man	I, or to outpatients if the physician particular drug regimen be asonably believes that a pharmacy the time of dispensation to the vices or within a 30-mile radius by
	89.2 The Where the prescriber including a controlled substance 17M-112 (Rev. 12/1822)		dispenses <u>a dangerous</u> drug <u>.</u> gency room patient, the following PIC Initials

conditions apply [BPC 4068(a)]:

**17M-112** (Rev. 1<del>2</del>/<del>18</del>22)

	17N	<b>1-112</b>	(Rev. 1 <del>2</del> / <del>18</del> <u>22</u> )	Page 42 of 44	PIC Initials
	<del>9.7</del> 8	<u>.8</u> Pati	ent package inserts are dispen	sed with all estrogen medicat	ions. [21 CFR 310.515]
	III o	r IV co sonabl	hospital pharmacy or drug roon ntrolled substance to the Dept y possible, but not more than a . [BPC 4068(a)(4), HSC 11165(d	t of Justice pursuant to HSC 1 seven days after the date a co	1165 as soon as
	ease	e-of-op	prescription drug is dispensed pening tested container, or in a scriber or patient. [15 USC 147	a non-complying package only	y pursuant to the request
			federal warning label <del>s</del> prohibi on container. [21 CFR 290.5]	ting transfer of controlled sub	ostances is on the
Yes No N//	<del>9.3</del> 8		prescriber ensures the label of CCR 1707.5.	n the drug contains all the inf	ormation required by BPC
Yes No N/A	8.3 · use		perating pharmacy has obtaine dministration and dispensing v		
			required by BPC section 4076	<u>).</u>	
		8.2.7	uninterrupted therapy when available or accessible, and sl The prescriber ensures that the	nall not exceed a 72-hour sup	ply. <del>=[BPC 4068(a)(1-6)]</del>
	□	<u>8.2.6</u>	reasonable believes that a ph and accessible at the time of The quantity dispensed is limit	armacy located outside the h dispensing to the patients.	ospital is not available
		<u>8.2.5</u>	information to the Departme and Safety Code.  The prescriber determines it is drug regimen be immediately	nt of Justice pursuant to Sect	ion 11165 of the Health atient that a particular
		<u>8.2.4</u>	pharmacy reopens. The hospital pharmacy retains schedule II, schedule III, or sc	•	
			The drugs <del>is <u>are</u></del> acquired by t The dispensing information is		pharmacy when the
	≝	<u>8.2.1</u>	when t-The hospital pharmacy hospital.	is closed and there is no pha	rmacist available in the

Yes No N/A	1		
	9.88.9 The hospital has written policie information regarding each drug give from a drug room, including the use warnings, and the importance of con	en at the time of dischargend and storage of each drug	ge or dispensed from a prescriber g, the precautions and relevant
	0.9 The operating pharmacy has obtain used for administration and dispension 4427.2(i)]		Board to operate the AUDS that is ddress of the AUDS location. [BPC
Yes No N/A	8.10 Medication guides are provided	on required medications	s. [21 CFR 208.1]
	8.11 Black box warning information is	s in conformance with 21	. CFR 201.57(c).
	8.12 Whenever an opioid prescription pharmacy or practitioner dispensing means of a flag or other notification "Caution: Opioid. Risk of overdose and the second second second second second second second second second sec	the drug prominently di mechanism attached to	splays on the label or container, by the container, a notice that states,
	CORRECTIVE ACTION OR ACTION PLA	AN AND COMPLETION DA	ATE
	SECTION 9 – AUDS THROUGH A FAC AUTHORITY TO PROVIDE PHARMAC DETENTION FACILITY, OR OTHER CO WITH THE FACILITY UNDER THE AUT	EUTICAL SERVICES (OR) RRECTIONAL FACILITY V	AUDS THROUGH A JAIL, YOUTH WHERE DRUGS ARE ADMINISTERED
	A. GENERAL REQUIREMENTS		
Yes No N/A	9.1 Review of the drugs contained we done in accordance with law and is to the review on a monthly basis, which inspection of the ADDS for cleanlines the security and accountability of the	he responsibility of the particular includes a physical inspars, and a review of all tra	pharmacy. A pharmacist conducts ection of the drugs in the ADDS, an insaction records in order to verify
	<u>Date of Last Review:</u>		
	CORRECTIVE ACTION OR ACTION PLA	AN AND COMPLETION DA	ATE
	<b>17M-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 43 of 44	PIC Initials

		B. PHARMACIST RESPONSIBILI	TIES:	
Yes No N/A				
		The stocking of an ADDS is perfo	rmed by a pharmacist. If t	he ADDS utilizes removable
				ingle dose containers, as defined
	<u>by t</u>	<u>he United States Pharmacopoeia</u>	a, the stocking system may	y be done outside of the facility
	<u>and</u>	be delivered to the facility, if all	the following conditions a	are met: [BPC 4427.65(c)(6)]
		0.2.1 The took of pleasing during	:	to courds duplicate on unit of use
				ts, cards, drawers, or unit of use
				acist, or by an intern pharmacist
		·		supervision of a pharmacist.
	<b>=</b>			se or single dose containers are  / in a secure tamper-evident
		container.	e priarmacy and the racinty	7 III a secure tamper-evident
		9.2.3 The facility, in conjunction	with the pharmacy has o	developed policies and
	=			cards, drawers, or unit of use or
			e properly placed into the	
		The pharmacist-in-charge of a ph	narmacy servicing an onsit	e or offsite ADDS ensures the
	tolle	owing: [CCR 1715.65(h)]		
		9.3.1 All controlled substances	added to an ADDS are acc	counted for
	=	5.5.1 7 III GOTTET OTTER GROSTATIONS	added to diffibbs die det	<del>50 arrea 1011</del>
		9.3.2 Access to the ADDS is lim	ited to authorized facility	personnel.
				access associated with controlled
		substances is performed		
		9.3.4 Confirmed losses of cont	='	orted to the board.
	COF	RECTIVE ACTION OR ACTION PL	AN AND COMPLETION DA	TF
	<u>co.</u>	MEETIVE METICIA ON METICIA I E	TIVY TIVE COIVII ELITOR BY	<u> </u>
		• DEVICE DE OLUBERATIO		
Yes No N/A		C. <u>DEVICE REQUIREMENTS:</u>		
<u>103 110 11/F</u>	2			
	9.4	ndividualized and specific access	s to the ADDS is limited to	facility and contract personnel
	<u>autl</u>	norized by law to administer dru	gs. [BPC 4427.65(c)(2)]	<del></del>
	17N	<b>1-112</b> (Rev. 1 <del>2</del> / <del>18</del> 22)	Page 44 of 44	PIC Initials

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

Yes No N/A	<del>-</del>
	9.5 A new drug order given by a prescriber for a patient of the facility for administration prior to
	the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are
	retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the
	<u>prescriber's order and the patient's profile for potential contraindications and adverse drug</u> <u>reactions. [BPC 4427.65(c)(4)(A)]</u>
	<u>reactions. [BPC 4427.03(C)[4][A]]</u>
	9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization
	and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC]
	4427.65(c)(4)(B)]
	<u>-1-27-03(e/, 1/LD/I)</u>
	9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee
	of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the
	ADDS pursuant to the order of the prescriber for emergency or immediate administration to
	the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the
	pharmacist. [BPC 4427.65(c)(4)(C)]
	When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is
	subject to the following requirements [BPC 4427.65(c)(5)]:
	0.9 The drugs removed from the ADDS for administration to a nations are in preparly labeled
<u> </u>	9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]
	antis of autimistration containers of packages. [b) ε 4427.05(ε/σ/μ)
	9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the
	ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the
	patient's profile for potential contraindications and adverse drug reactions. [BPC
	4427.65(c)(5)(B)]
	9.10 The pharmacy providing services to the facility controls the access to the drugs stored in
	the ADDS. [BPC 4427.65(c)(5)(C)]
	9.11 After the pharmacist reviews the prescriber's order, access by licensed personnel to
	the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist
	and that are specific to the patient. When the prescriber's order requires a dosage variation of
	the same drug, licensed personnel has access to the drug ordered for that scheduled time of
	administration. [BPC 4427.65(c)(5)(F)]
	9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not
	patient specific in their design, shall be allowed if the ADDS has electronic and mechanical
	safeguards in place to ensure the drugs delivered to the patient are specific to the patient.

**17M-112** (Rev. 1<del>2</del>/<del>18</del>22)

Page 45 of 48

PIC Initials \_\_\_\_\_

	[BPC 4427.65(c)(5)(G)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/	D. <u>RECORD KEEPING REQUIREMENTS</u>
	9.13 Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years. [BPC 4427.65(c)(1)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE
Yes No N/A	E. POLICIES AND PROCEDURES
	9.14 The pharmacy operating the AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the ADDS. [BPC 4427.65(b)]
	9.15 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)
	9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]
	CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

**17M-112** (Rev. 1<del>2</del>/<del>18</del>22)

Page 46 of 48

PIC Initials \_\_\_\_\_

## **CERTIFICATION ACKNOWLEDGMENT**

PHARMACIST-IN-CHARGE	CERTIFICATION:	
I, (please print)	, RPH #_	hereby certify that I have
completed the self-assessr pharmacist-in-charge. Any responses are subject to ve	nent of this automated drug d deficiency identified herein w erification by the Board of Pha e State of California that the i	elivery system of which I am the ill be corrected. I understand that all rmacy. I further state under penalty nformation that I have provided in
Signature (Pharmacist-in	-Charge)	
ACKNOWLEDGMENT BY O	WNER OF ADDS:	
the State of California that understand that failure to	I have read and reviewed this correct any deficiency identific	nder penalty of perjury of the laws of completed self-assessment. I ed in this self-assessment could resuli 's license issued by the California
Signature	Date	

## **CERTIFICATION OF COMPLETED ACTION PLAN**

PHARMACIST-IN-CHARGE	ECERTIFICATION:	
corrected the deficiencies system of which I am the verification by the Board of	pharmacist-in-charge. I underst of Pharmacy. I further state und	hereby certify that I have nt of this automated drug delivery and that all responses are subject to der penalty of perjury of the laws of ovided in this self- assessment form
Signature(Pharmacist-i	n-Charge)	
ACKNOWLEDGMENT BY	OWNER OF ADDS:	
the State of California tha understand that failure to	It I have read and reviewed this ocorrect any deficiency identified utomated drug delivery system?	nder penalty of perjury of the laws of completed self-assessment. I ed in this self-assessment could result 's license issued by the California
Signature	Date	