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



AUTOMATED DRUG DELIVERY SYSTEM (ADDS) SELF-ASSESSMENT

Business and Professions Code section 4102 requires the pharmacist-in-charge of the pharmacy operating the ADDS to complete a self-assessment to assess the pharmacy's compliance with federal and state laws identified on the self-assessment form. **The self-assessment shall be performed by July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days of any of the following: (1) a new pharmacy license is issued; (2) there is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy; (3) there is a change in the location of the pharmacy to a new address; (4) a new ADDS license has been issued; and (5) there is a change in the licensed location of an ADDS to a new address.**¹ The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Please mark the appropriate box (Yes, No, or N/A) for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If the specific legal requirement referenced in the question clearly and objectively does not apply to your pharmacy, then mark the box "N/A". If more space is needed, you may add additional sheets. The self-assessment must be completed in its entirety. It may be completed online and printed, initialed, and signed (use original signatures or digital signatures that comply with California Code of Regulations, title 16, section 1700). The completed form shall be kept on file in the pharmacy and made available to the Board upon request. A new self-assessment form must be filled out each time the self-assessment process is required to be completed; do not use or copy from a previous self-assessment form. Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Notes:

- **For a hospital pharmacy** operating an AUDS pursuant to BPC 4427.2(i): if all conditions set forth in the first sentence of BPC 4427.2(i) are met, the AUDS is exempt from the requirement of obtaining an ADDS license. However, the AUDS shall comply with all other requirements for an ADDS set forth in Article 25 of Chapter 9 of Division 2 the BPC (BPC 4427-4427.8), and the PIC of the hospital pharmacy must still complete the self-assessment pursuant to BPC 4102(d)(3).

The PIC may complete a single self-assessment for all unlicensed AUDS if the devices are made by the same

¹ See BPC 4102(d)(3); see also CCR 1715.1(b).

manufacturer, are controlled by the same software system on a single server, and use the same policies and procedures. Attach a list of all unlicensed AUDDS, their locations, and their hours of operation.

- **For a correctional pharmacy** operating more than one licensed ADDS at a single institution, the PIC may complete a single self-assessment for all licensed ADDS, if the devices are made by the same manufacturer, are controlled by the same software system on a single server, and use the same policies and procedures.
- An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. If a pharmacy uses such technology, and does not otherwise operate a licensed or unlicensed ADDS, the pharmacy is not required to complete the ADDS Self-Assessment.
- This self-assessment is not an all-inclusive compilation of all pharmacy laws and regulations. The pharmacist-in-charge is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy, regardless of whether such laws or regulations are referenced on this self-assessment.

Pharmacy Name:				
Address:		Telephone:		
Pharmacy License #:		Expiration Date:		
DEA Registration #		Expiration Date:		
Date of DEA Inventory		Date of Last Controlled Substance Inventory Reconciliation Report (CCR 1715.65(c))		
Pharmacy Hours:	Weekdays	Saturday	Sunday	24 Hours
Pharmacist-in-Charge		License#:		
		Expiration Date:		

Location of ADDS: Check all that apply	
AUDS:	
<input type="checkbox"/>	A health facility licensed pursuant to HSC 1250 that complies with HSC 1261.6.
<input type="checkbox"/>	A correctional clinic licensed pursuant to BPC 4187.1.
<input type="checkbox"/>	A correctional clinic licensed pursuant to BPC 4187.1.
<input type="checkbox"/>	A facility with statutory authority to provide pharmaceutical services.
<input type="checkbox"/>	Jail, youth detention facility or other correctional facility where drugs are administered with the facility.
APDS:	
<input type="checkbox"/>	Adjacent to the secured pharmacy area of the pharmacy.
<input type="checkbox"/>	Clinic licensed pursuant to HSC 1204 or 1204.1, or BPC 4180 or 4190.
<input type="checkbox"/>	Medical office or other location where patients are regularly seen for purposes of diagnosis and treatment used to dispense to patients of the practice.
<input type="checkbox"/>	Premises of a covered entity or premises of medical professional practice under contract to provide medical services to covered entity patients.

References:

Abbreviation	Full Reference
ADDS	Automated Drug Delivery Systems of all types (includes APDS and AUDS)
APDS	Automated Patient Dispensing System
AUDS	Automated Unit Dose System
BPC	California Business and Professions Code
CC	California Civil Code
CCR	Title 16 California Code of Regulations
CDCR	California Department of Corrections and Rehabilitation
CFR	Code of Federal Regulations
HRSA	Health Resources and Services Administration
HSC	California Health and Safety Code
PC	California Penal Code
PIC	Pharmacist-in-Charge
USC	United State Code
WIC	California Welfare and Institutions Code

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- A medical office or other location where patients are regularly seen for purposes of diagnosis and treatment
- A clinic licensed pursuant to HSC 1204 or 1204.1, or BPC 4180 or 4190

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- Hospital Pharmacy: AUDS used for dispensing to a patient pursuant to BPC 4068
- Drug Room: AUDS used for dispensing to a patient pursuant to BPC 4056

Section 7: AUDS in Other Authorized Locations:

- A facility licensed by California with the statutory authority to provide pharmaceutical services
- Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director

(Note: These are correctional facilities not under the jurisdiction of CDCR.)

Section 1: General Requirements for All Types of ADDS

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.1	BPC 4427.2(a) BPC 4427.4(a)	The ADDS is installed, leased, owned, or operated in California, is licensed by the Board (unless an exemption from licensure applies), and, if licensed, is owned or leased by the pharmacy holding the license.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.2	BPC 4427.2(d) CCR 1715.6 CCR 1715.65 21 CFR 1301.76	The use of the ADDS is consistent with legal requirements, the ADDS is secure from access and removal by authorized individuals, the pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion, and the pharmacy's policies and procedures include provisions for reporting to the Board and the DEA drug losses from the ADDS inventory, as required by law.				
1.3	BPC 4427.3(c) BPC 4427.65(c) HSC 1261.6(d)	The pharmacy holding the ADDS license and the location where the ADDS is placed have 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.				
1.4	BPC 4427.4(b) BPC 4427.4(c)	Each ADDS is operated under the supervision of the pharmacy holding the ADDS license and the pharmacy understands that the ADDS is considered an extension and part of the pharmacy holding the ADDS license.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.5	BPC 4427.4(d)	The pharmacy understands that drugs and devices stored in an ADDS are deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and that drugs and devices dispensed from the ADDS are considered to have been dispensed by that pharmacy.				
1.6	BPC 4119.11(g) BPC 4427.4(e) HSC 1261.6(g)	The stocking and restocking of an ADDS is performed only by authorized individuals as permitted by law.				
1.7	BPC 4427.4(e) BPC 4427.65(c) BPC 4119.11(e) BPC 4119.11(f) HSC 1261.6(f)	Access to the ADDS is controlled and tracked using an identification or password system or biosensor and 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.				
1.8	BPC 4427.4(f)	Drugs or 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 with the ADDS location and upon retrieval of the drugs and devices from secured storage, an inventory is taken to detect any losses or overages.				
1.9	BPC 4427.5	Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.10	BPC 4081 BPC 4105 BPC 4113.1(a) BPC 4119.11(a) BPC 4427.4 BPC 4427.65(c) BPC 4427.7 CCR 1713 CCR 1717.1 CCR 1717.5 CCR 1764 CC 56.101 HSC 1261.6(b)	Pharmacy records related to the use of ADDS are maintained within the licensed pharmacy, readily retrievable, and separate from other pharmacy records, as required by law.				
1.11	BPC 4113.1(a) BPC 4125 BPC 4427.7(b) CCR 1711(f)	The pharmacy has a quality assurance program and reports ADDS medication errors as required by law.				
1.12	CCR 1715.65 BPC 4427.4(c) BPC 4427.4(d) 21 CFR 1304.04 21 CFR 1304.11	The pharmacy performs periodic inventory activities and prepares inventory reconciliation reports for controlled substances stocked in the ADDS as required by law.				

COMPLETE THE FOLLOWING SECTION(S) AS THEY APPLY TO THE TYPE OF ADDS OPERATED BY YOUR PHARMACY.

SECTION 2: APDS in Covered Entities or Contracted with a Covered Entity [BPC 4119.11]

SECTION 3: APDS in Other Authorized Locations:

- Adjacent to the secured pharmacy area
- A medical office or other location where patients are regularly seen for purposes of diagnosis and treatment
- A clinic licensed pursuant to HSC 1204 or 1204.1, or BPC 4180 or 4190

SECTION 4: AUDS in a Health Facility Licensed Pursuant to HSC 1250 That Complies with HSC 1261.6 (For Administration in the Facility)

SECTION 5: AUDS Operated by a CDCR Correctional Clinic Licensed Pursuant to BPC 4187.1

SECTION 6: AUDS in a Hospital Pharmacy or Drug Room (For Dispensing to a Patient for use Outside the Facility):

- Hospital Pharmacy: AUDS used for dispensing to a patient pursuant to BPC 4068
- Drug Room: AUDS used for dispensing to a patient pursuant to BPC 4056

SECTION 7: AUDS in Other Authorized Locations [BPC 4427.65(a)]:

- A facility licensed by California with the statutory authority to provide pharmaceutical services
- Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director. (Note: These are correctional facilities not under the jurisdiction of CDCR.)

Section 2: APDS in Covered Entities or Contracted with a Covered Entity [BPC 4119.11]

A. General Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.1	BPC 4119.11(a) BPC 4126(a)	The pharmacy operating the APDS located on the premises of the covered entity (or on the premises of a medical professional practice under contract to provide medical services to covered entity patients) is under contract with the covered entity to provide pharmacy services to patients of the covered entity through the use of the APDS, and the contract complies with HRSA guidelines and is available for inspection by Board staff during normal business hours.				
2.2	BPC 4126(b)	All records of acquisition and disposition of drugs purchased pursuant to 42 USC 256b for use in the ADDS and received by the pharmacy are segregated from the pharmacy's other drug stock by physical or electronic means and are readily retrievable in a form separate from the pharmacy's other records.				
2.3	BPC 4126(c)	Drugs obtained by the pharmacy for the ADDS to be dispensed to patients of the covered entity pursuant to 42 USC 256b that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy are returned to the distributor from which they were obtained.				

B. Pharmacy Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.4	BPC 4081(e) BPC 4119.11(d) CCR 1713(f)	The pharmacy holding the APDS license maintains the written APDS policies and procedures for 3 years after the last date of use of that APDS.				
2.5	BPC 4119.11(a)	The pharmacy is solely responsible for the security, operation, and maintenance of the APDS.				

C. Pharmacist Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.6	BPC 4119.11(a)	The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity.				
2.7	BPC 4119.11(h)	On a monthly basis, a pharmacist conducts a review of the drugs contained within, and the operation and maintenance of, the APDS, and such review includes a physical inspection of the drugs in the APDS, an inspection of the APDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.				

D. Device Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.8	BPC 4119.11(e)	If the APDS is accessed via password system, it includes a camera that records a picture of the person accessing the machine and this picture is kept for at least 180 days.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.9	BPC 4119.11(c)	The APDS collects, controls, and maintains all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability, and transaction information is readily available in a downloadable format for review and inspection by individuals authorized by law.				
2.10	BPC 4119.11(d)	The APDS is only used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an APDS and whose use of the APDS meet the criteria pursuant to paragraph (1) of subdivision (d) of BPC 4119.11.				
2.11	BPC 4119.11(d)	The APDS has a means to identify each patient and only releases the identified patient's drugs and devices to the patient or the patient's agent.				
2.12	BPC 4119.11(d)	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.				
2.13	BPC 4119.11(d)	All prescribed drugs and devices dispensed from the APDS for the first time are accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video.				
2.14	BPC 4119.11(d)	The APDS includes a notice, prominently posted on the APDS, that provides the name, address, and telephone number of the pharmacy that holds the APDS license for that APDS.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.15	BPC 4119.11(d) BPC 4076 CCR 1717 CCR 1707.5 15 USC 1473(b) 21 CFR 290.5 21 CFR 310.515 21 CFR 208.1 21 CFR 208.24 21 CFR 201.57	All drugs dispensed by the APDS are appropriately labeled, and appropriate warning labels are affixed. Medication guides and package inserts are provided as required by law.				

E. Policies and Procedures

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.16	BPC 4119.11(d) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures with respect to maintaining the security of the APDS and dangerous drugs and devices within the APDS.				
2.17	BPC 4119.11(d) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures with respect to determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients, including when consultation is needed.				
2.18	BPC 4119.11(d) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures with respect to ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.19	BPC 4119.11(d) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures with respect to describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location whether the APDS is placed, regarding maintenance and filing procedures for the APDS.				
2.20	BPC 4119.11(d) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures with respect to orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices.				
2.21	BPC 4119.11(d) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures with respect to ensuring delivery of drugs and devices to patients expecting to receive them from the APDS if the APDS is disabled or malfunctions.				

Section 3: APDS in Other Authorized Locations

Check the appropriate box(es):

- Adjacent to the secured pharmacy area
- A medical office or other location where patients are regularly seen for purposes of diagnosis and treatment
- A clinic licensed pursuant to HSC 1204 or 1204.1, or BPC 4180 or 4190

A. General Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	BPC 4427.6(l) CCR 1713(f)	The pharmacy holding the APDS license maintains the written policies and procedures pertaining to the APDS for 3 years after the last date of use of that APDS.				

B. Pharmacist Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.2	BPC 4427.6(d)	A pharmacist licensed by the Board performs all clinical services conducted as part of the APDS dispensing process, including, but not limited to, drug utilization review and consultation.				
3.3	BPC 4427.6(e)	Drugs are dispensed from the APDS only upon authorization by a licensed pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.				
3.4	BPC 4427.6(f) CCR 1713(d)	All prescribed drugs and devices dispensed to a patient from an APDS for the first time are accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video.				
3.5	BPC 4427.6(b) CCR 1713(d)	A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to that patient.				

C. Device Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.6	BPC 4427.6(b)	The APDS is only used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an APDS.				
3.7	BPC 4427.6(c)	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.				
3.8	BPC 4427.6(g)	The APDS includes a notice, prominently posted on the APDS, providing the name, address, and telephone number of the pharmacy that holds the ADDS license for that APDS.				
3.9	BPC 4427.6(j)	The APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and is only used to dispense dangerous drugs and dangerous devices to patients of the practice.				
3.10	BPC 4427.6(h) BPC 4076 CCR 1717 CCR 1707.5 15 USC 1473(b) 21 CFR 290.5 21 CFR 310.515 21 CFR 208.1 21 CFR 208.24 21 CFR 201.57	All drugs and devices dispensed by the APDS are appropriately labeled, and appropriate warning labels are affixed. Medication guides and package inserts are provided as required by law.				

D. Policies and Procedures

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.11	BPC 4427.6(a) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures regarding maintaining the security of the APDS and the dangerous drugs and devices within the APDS.				
3.12	BPC 4427.6(a) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures regarding determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.				
3.13	BPC 4427.6(a) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures regarding ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.				
3.14	BPC 4427.6(a) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures regarding 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.				
3.15	BPC 4427.6(a) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures regarding orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.16	BPC 4427.6(a) CCR 1713(e)	The pharmacy has developed and implemented written policies and procedures regarding ensuring the delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.				
3.17	BPC 4427.6(a) CCR 1713(e)	The pharmacy's written policies and procedures pertaining to the APDS are reviewed annually.				

**Section 4: AUDS in a Health Facility Licensed Pursuant to HSC 1250 That Complies with HSC 1261.6
(For Administration in the Facility)**

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

A. General Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	HSC 1261.6(h)	The pharmacy is responsible for review of the drugs contained within the AUDS and the operation and maintenance of the AUDS.				
4.2	HSC 1261.6(i)	If the drugs placed in the AUDS are in unit dose packaging or unit of use, the information required by BPC 4076 and HSC 111480 is readily available at the time of drug administration.				
4.3	HSC 1261.6(c)	Individualized and specific access to the AUDS is limited to facility and contract personnel authorized by law to administer drugs.				
4.4	HSC 1261.6(e)	When used as an emergency pharmaceutical supplies container, drugs removed from the AUDS are limited to those specified in HSC 1261.6(e).				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.5	HSC 1261.6(f)	Drugs removed from the AUDS for administration to a patient are in properly labeled units of administration containers or packages. After the pharmacist reviews the prescriber's order, access by licensed personnel to the AUDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient.				

B. Pharmacist Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.6	HSC 1261.6(f)	A pharmacist reviews and approves all orders prior to a drug being removed from the AUDS for administration to a patient. The pharmacist reviews the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.				
4.7	HSC 11159.2 HSC 11159.3 HSC 11162.1 HSC 11164 HSC 11167.5	For long term care and hospice facilities, all written controlled substances prescriptions for drugs dispensed from the AUDS are on California Security Prescription Forms and signed and dated by the prescriber, unless other exceptions exist.				
4.8	HSC 1261.6(h)	On a monthly basis, a pharmacist conducts a review of the drugs contained within, and the operation and maintenance of, the AUDS, and such review includes a physical inspection of the drugs in the AUDS, an inspection of the AUDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.				

C. Policies and Procedures

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.9	HSC 1261.6(d) BPC 4427.3(c)	The facility and the pharmacy have developed and implemented written policies and procedures which define access to the AUDS and limits to access to equipment and drugs. The policies and procedures are maintained at the pharmacy and the location where the AUDS is being used.				
4.10	HSC 1261.6(g) BPC 4427.3(c)	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 AUDS.				

Section 5: AUDS Operated by a CDCR Correctional Clinic Licensed Pursuant to BPC 4187.1

A. General Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	BPC 4187(a) BPC 4187.1(d) BPC 4187.5(a) BPC 4187.5(f)	The AUDS is located in a licensed correctional clinic operated by the state to provide health care to eligible patients of the CDCR and is operated by a licensed correctional pharmacy.				
5.2	BPC 4187.1(a) BPC 4187.2	The licensed correctional clinic obtains drugs for the AUDS only from entities as specified in law.				
5.3	BPC 4187.1(b)	The dispensing or administering of drugs in the correctional clinic for the AUDS is performed pursuant to a chart order, a valid prescription, or an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.4	BPC 4187.1(b)	Drugs dispensed from the AUDS to patients that are to be kept on the patient's person for use meet the labeling requirements of BPC 4076 and all recordkeeping requirements of Chapter 9 of Division 2 of the BPC.				

B. Policies and Procedures

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.5	BPC 4187.5(a)	The correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the California Correctional Health Care Services Health Care Department Operations Manual to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs, and all policies and procedures are maintained either in electronic form or paper form at the location where the AUDS is being used.				

C. Pharmacist Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.6	BPC 4187.5(b)	Drugs are removed from the AUDS only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions, except as otherwise permitted by law. Any removal of medication from the AUDS prior to the pharmacist review is documented and provided to the correctional pharmacy when it reopens.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.7	BPC 4187.5(e)	On a monthly basis, a pharmacist conducts a review of the drugs contained within, and the operation and maintenance of, the AUDS, and such review includes a physical inspection of the drugs in the AUDS, an inspection of the AUDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.				

D. Device Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.8	BPC 4187.5(c) BPC 4187.5(d) BPC 4187.5(g)	Drugs from the AUDS are only removed by a person authorized to stock the AUDS, or by a person lawfully authorized to dispense or administer the drugs.				
5.9	BPC 4187.5(e)	Review of the drugs contained within, and the operation and maintenance of, the AUDS is the responsibility of the correctional clinic.				
5.10	BPC 4187.5(f)	Any drugs within the AUDS are considered owned by the licensed correctional pharmacy until they are dispensed from the AUDS.				

SECTION 6: AUDS Operated by a Hospital Pharmacy or Drug Room (For Dispensing to a Patient for Use Outside the Facility):

Check the appropriate box:

- HOSPITAL PHARMACY: AUDS used for dispensing to a patient pursuant to BPC 4068
- DRUG ROOM: AUDS used for dispensing to a patient pursuant to BPC 4056

Note: Hospital pharmacies and drug rooms must also complete Section 4 for AUDS used for administration to patients while in the facility. This Section 6 addresses additional requirements for hospital pharmacies and drug rooms operating an AUDS used for dispensing to patients for use outside the facility.

A. General Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.1	BPC 4056	If the hospital is an exempt hospital which does not employ a full-time pharmacist and has a licensed drug room, the AUDS is used for drugs for administration under the direction of, or for dispensation by, a physician, in compliance with law.				
6.2	BPC 4068	If the hospital is not an exempt hospital (i.e., has a licensed hospital pharmacy), the AUDS is used in an emergency room when the hospital pharmacy is closed and there is no pharmacist available in the hospital and contains drugs acquired by the hospital pharmacy; the dispensing information is recorded and provided to the pharmacy when the pharmacy reopens; and the pharmacy retains the dispensing information.				
6.3	BPC 4068(a) HSC 11165	Dispensing information with respect to controlled substances dispensed from the AUDS is reported to CURES as required by law.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.4	BPC 4056 BPC 4068 BPC 4074 BPC 4076 BPC 4076.5 BPC 4076.6 BPC 4076.7 BPC 4076.8 CCR 1707.5 CCR 1717 CCR 1744 21 CFR 310.515 21 CFR 208.24 21 CFR 290.5	Drugs dispensed from the AUDS are appropriately labeled, and appropriate warning labels are affixed. Medication guides and package inserts are provided as required by law.				
6.5	15 USC 1473 16 CFR 1700.15	Drugs dispensed from the AUDS comply with child-resistant container and senior-adult ease-of-opening tested container requirements.				

Section 7: AUDS in Other Authorized Locations:

Check the appropriate box:

- A facility licensed by California with statutory authority to provide pharmaceutical services
- Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.
- (Note: These are correctional facilities not under the jurisdiction of CDCR.)

A. General Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.1	BPC 4427.65(c)	The pharmacy operating the AUDS is responsible for review of the drugs contained within, and the operation and maintenance of, the AUDS.				

B. Pharmacist Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.2	HSC 11159.2 HSC 11159.3 HSC 11162.1 HSC 11164	All written controlled substances prescriptions for drugs dispensed from the AUDS are on California Security Prescription Forms and signed and dated by the prescriber, unless other exceptions exist.				
7.3	HSC 11167	The pharmacy is in compliance with the limitations for dispensing a schedule II prescription for drugs dispensed from the AUDS upon an oral order, in an emergency.				
7.4	BPC 4427.65(c)	On a monthly basis, a pharmacist conducts a review of the drugs contained within, and the operation and maintenance of, the AUDS, and such review includes a physical inspection of the drugs in the AUDS, an inspection of the AUDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.				
7.5	BPC 4427.65(c)	A pharmacist reviews and approves all orders prior to a drug being removed from the AUDS for administration to a patient. The pharmacist reviews the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.				

C. Device Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.6	BPC 4427.65(c)	Individualized and specific access to the AUDS is limited to facility and contract personnel authorized by law to administer drugs.				
7.7	BPC 4427.65(c)	When used as an emergency pharmaceutical supplies container, drugs removed from the AUDS, are limited to those specified in BPC 4427.65(c)(4).				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.8	BPC 4427.65(c)	Drugs removed from the AUDS for administration to a patient are in properly labeled units of administration container or packages. After the pharmacist reviews the prescriber's order, access by licensed personnel to the AUDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient.				
7.9	BPC 4427.65(c)	Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if those systems have electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to that patient.				

D. Policies and Procedures

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.10	BPC 4427.65(b)	The pharmacy operating the AUDS has developed and implemented, and annually reviews, written policies and procedures pertaining to the AUDS.				
7.11	BPC 4427.65(c) BPC 4427.3(c)	All policies and procedures are maintained at the pharmacy operating the AUDS and the location where the AUDS is being used.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.12	BPC 4427.65(c)	If the AUDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, and the stocking system is done outside of the facility and delivered to the facility, 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 AUDS.				

Additional References

Licensees are encouraged to review the additional references provided below for more information about the listed topics. Licensees are advised that the below is a list of selective references that licensees may find helpful, but not an exhaustive list of all pharmacy laws and regulations that may apply to any given topic or in any specific case.

Reference	Topic
CCR 1708.1	Temporary Closures
BPC 22949.92.1	Pharmacy Closures

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I am the pharmacist-in-charge of the pharmacy operating the ADDS and that I have completed this self-assessment to the best of my professional ability. Any deficiency identified herein will be corrected by _____ (date). I understand that all responses are subject to verification by the Board of Pharmacy. I acknowledge the self-assessment will be readily available for review during any inspection by the Board. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature* _____
(Pharmacist-in-Charge)

Date: _____

ACKNOWLEDGEMENT BY OWNER OR AUTHORIZED OFFICER OF THE PHARMACY:

I, (please print) _____, hereby certify that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in action by the California State Board of Pharmacy.

Signature* _____
Owner or Authorized Officer of the Pharmacy

Date: _____

*Consistent with [16 CCR Section 1700](#), the Board will accept digital signatures.