



SANTA BARBARA COUNTY
DEPARTMENT OF
Behavioral Wellness
A System of Care and Recovery

**Programmatic
Policy and Procedure**

Section	Psychiatric Health Facility (PHF)	Effective:	4/6/11
Sub-section	Nursing	Version:	3.0
Policy	Controlled Substance Management	Last Revised:	DRAFT
Director's Approval	_____	Date	_____
	Alice Gleghorn, PhD		
PHF Medical Director's Approval	_____	Date	_____
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Supersedes:	Controlled Substance Management rev. 9/28/2016; Controlled Substance Delivery Log rev. 3/14/2012	Audit Date:	DRAFT
Approvals:			

1. PURPOSE/SCOPE

- 1.1. To provide standards and procedures for the safe inventory, management and administration of controlled substances at the Santa Barbara County Psychiatric Health Facility (hereafter the "PHF").
- 1.2. To ensure PHF medication management policies are in compliance with all federal and state laws and standards of professional practice.

2. DEFINITIONS

The following terms are limited to the purposes of this policy:

- 2.1. **Licensed nursing staff (LNS)** – an individual employed or contracted by the PHF who holds a valid California license as a: registered nurse (RN); licensed vocational nurse (LVN); or licensed psychiatric technician (LPT).
- 2.2. **Schedule II, III-V controlled substances** – a classification of drugs as defined by the United States Controlled Substances Act that have a high potential for abuse and may lead to physical and psychological dependence. Schedules can be found on-line at <https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm>, or under Title 21 of the United States Code, Controlled Substances Act, Chapter 13, Part B, Section 812.
- 2.3. **Pyxis MedStation** – an automated dispensing system that performs the storage, dispensing, and distribution of medications.

2.4. **Blind Count** – when a user of the Pyxis MedStation system physically counts the inventory of that medication prior to removing said medication from the bin. In a blind count, the system does not display the count, so the user will not know whether they are witnessing a discrepancy.

2.5. **Verified Count** – in this type of count, the Pyxis MedStation system will display the expected count. Staff will then confirm this count or will make note of any discrepancy.

3. POLICY

3.1. Controlled substances shall be controlled in a manner that ensures patient safety and permits full auditing of the product from receipt through to patient administration. The records shall be available for inspection.

3.2. Medications classified by the Drug Enforcement Administration (DEA) as Schedule II and III-V controlled substances shall be subject to special management, oversight and accountability. In accordance with all relevant federal and state laws and regulations, the PHF shall enforce strict controls in the access, storage, record-keeping and disposal of controlled substances.

3.3. The PHF utilizes the Pyxis MedStation, an automated medication dispensing system or unit dose medication system. In accordance with Title 22 regulations, controlled substances that are supplied on a scheduled basis as a part of a unit dose medication system do not require separate locked storage from non-controlled medications. However, to support oversight and accountability, all controlled substances stored in the Pyxis MedStation will be in separate bins from non-controlled medications.

3.4. Medications listed in Schedules II and III-V shall not be accessible to employees other than licensed nursing, pharmacy and medical personnel as designated by PHF management.

3.5. Shift change counts are not required for controlled substances stored within the Pyxis MedStation. Shift change counts are required in the event the Pyxis MedStation experiences downtime and medications must be accessed manually, or if controlled substances are stored outside the Pyxis MedStation.

3.6. Records for controlled substances administration and inventory logs are legal documents and must legally be retained for a period of at least ~~three (3) years~~ 10 years from the term end date of the contract with the Department of Health Care Services (DHCS), or in the event the PHF has been notified that an audit or investigation of the contract has been commenced, until such time as the matter under audit or investigation has been resolved, including the exhaustion of all legal remedies, whichever is later. [42 CFR §438.3(h), 438.230(c)(3)(i-iii)]

4. **STORAGE AND ACCESS**

4.1. All controlled substances will be stored in the PHF's designated medication room.

4.2. Controlled substances that require refrigeration will be stored in a refrigerator outfitted with a lock.

4.3. For those controlled substances stored outside of the Pyxis MedStation, a dedicated Medication Nurse will be assigned to hold the key to these storage areas.¹

1. The controlled substance key will be turned over to the shift's Team Leader for the duration of the Medication Nurse's scheduled break.

4.4. If keys to the medication storage areas are lost, or the locking mechanism is damaged and does not lock properly, the PHF Team Lead will report this to the PHF Nursing Supervisor or the on-call administrator immediately. The PHF Team Lead will take any security precautions necessary to mitigate unauthorized access to the medication room during this time, including but not limited to relocating medications to another secure area of the facility or assigning staff to monitor the medication room entrance until the keys are located or the door lock is repaired.

5. **SHIFT COUNT FOR NON-PYXIS MEDSTATION MEDICATIONS**

5.1. At each shift change, a count of all controlled substances will be conducted by the incoming and outgoing Medication Nurses for those medications stored outside the Pyxis MedStation.² The completion of the count will be documented on the *Controlled Drug Count Sheet* (see Attachment A) by both staff. Both staff members must verify by:

1. Reviewing that all controlled substances removed from storage since the last count are accurately and completely documented. This includes confirming that the quantities deducted from the perpetual inventory are consistent with the dose administered and that any disposal has been cosigned as being witnessed.
2. Both Medication Nurses must visually examine the actual controlled substance products and verify the amount remaining is correct.

5.2. If a discrepancy is discovered, a recount must be performed. If the discrepancy is not resolved with a recount, staff will follow discrepancy investigation and reporting procedures as listed in Section 9 of this policy.

¹ For more information on medication key tracking, please refer to the PHF's "Access to Medication Storage Areas" policy.

² For more information, please see the "Pyxis MedStation Controlled Substances" policy.

6. **PYXIS MEDSTATION COUNTS AND COUNT VERIFICATIONS**

- 6.1. Before a controlled substance can be withdrawn from the Pyxis MedStation for administration to a patient, the doses must be subjected to a blind count.
1. Each time a controlled substance is accessed, the Medication Nurse will be prompted to enter a blind count. The Medication Nurse will count the medication and enter the physical count they record.
 2. If the Medication Nurse enters a quantity that is different from the count that the system expects, a discrepancy will be recorded and must be resolved by the end of the shift. The Medication Nurse may still administer controlled substances prior to resolving the discrepancy.
 3. The PHF Team Lead will be informed of any unresolved discrepancies and will assist in the resolution and/or reporting of these discrepancies as required.
- 6.2. Each week, a verified count on all controlled substances will be performed. The verified count must be completed by a pharmacist and either one (1) LNS or one (1) other Pharmacy staff (e.g., pharmacist, pharmacy technician). The pharmacist will print a report documenting the verified count. Verified count reports will be stored onsite or at the Pharmacy for a minimum of 10 years.
- 6.3. Pharmacy staff will maintain an ongoing record of discrepancies or unusual access associated with controlled substances.
- 6.4. No end-of-shift count is required for controlled substances stored in the Pyxis MedStation except in the event of a system downtime period. Please see the Pyxis MedStation Downtime policy for further information.

7. **CONTROLLED SUBSTANCE ADMINISTRATION**

- 7.1. When a controlled substance is administered, the Medication Nurse will enter the date and time of administration on the patient's Medication Administration Record (MAR). The Medication Nurse will sign and/or initial **this form** where indicated.
- 7.2. Controlled substances removed from the Pyxis MedStation but not administered to the patient and still in the original unit dose packaging will be returned to the bin designated specifically for returned controlled substances. A second LNS is required as a witness when returning controlled medications.
- 7.3. If the original unit dose packaging is not intact, the controlled medication cannot be returned to the Pyxis MedStation and must be disposed.
1. Disposal for controlled medications removed from the Pyxis MedStation must be documented within the Pyxis MedStation system.
 2. Please see PHF policy "Medication Disposal **and Destruction**" for further details.

8. **CONTROLLED SUBSTANCES AT DISCHARGE**

- 8.1. At discharge, controlled substances that are the patient's own medications will be processed according to the PHF's "Patients' Own Medications" policy.
- 8.2. After a patient is discharged, any remaining controlled medications prescribed for that patient will be disposed.
 1. Please see PHF policy "Medication Disposal and Destruction" for further details.

9. **REPORTING AND DOCUMENTING DISCREPENCIES**

- 9.1. During the course of the shift, the person discovering the discrepancy is responsible for resolving the discrepancy. The PHF Team Lead will be responsible for ensuring the discrepancy is resolved by the end of the shift.
 1. The PHF Team Lead may refer to the Pyxis User Manual for Pyxis MedStation discrepancy resolution procedures.
- 9.2. Any unresolved discrepancy in the count of a controlled substance must be reported immediately to the Nursing Supervisor or on-call administrator.
- 9.3. An Unusual Occurrence Incident Report must be completed by discovering staff once it is determined that the discrepancy cannot be resolved, but no later than the end of the shift.
 1. If the unresolved discrepancy is for a controlled substance stored in the Pyxis MedStation, discovering staff must also complete the *Controlled Substances Discrepancy Resolution Report (DRR)* (Attachment B) in addition to the Unusual Occurrence Incident Report.
 2. Completed reports will be forwarded to the PHF Nursing Supervisor, PHF Medical Director, PHF Program Manager and PHF Quality Care Management (QCM) Coordinator.
 3. A determination will be made by these parties in regards to any disciplinary action, possible notification of local law enforcement and any other actions and interventions.
- 9.4. PHF Leadership, the Pharmacist-in-Charge, or a designee will submit incident findings and recommendations to the Quality Assessment and Performance Improvement (QAPI) Committee and/or the PHF Medical Practice Committee (MPC).
- 9.5. The PHF Nursing Supervisor or a designee shall complete the Reporting Theft or Loss of Controlled Substances form (DEA-106) online for any unexplained loss, or for any theft or suspected theft of a controlled substance, within 14 days of discovery of the loss or theft. The PHF Nursing Supervisor will forward a copy of the completed form to the Santa Barbara County Mental Health Services Pharmacy for informational purposes.
 1. The form can be found at this web address:
<https://apps.deadiversion.usdoj.gov/webforms/app106Login.jsp>

REFERENCE

Code of Federal Regulations

Title 21, Section 1317.95

Title 42, Sections 482.25(a)(3), (b)(2)(ii), (b)(7); Section 438.3(h)

United States Code - Controlled Substances Act

Title 21, Sections 801, 812 and 813

California Code of Regulations – Social Security

Title 22, Section 77079.9

U.S. Department of Justice & Drug Enforcement Administration

Diversion Control Division, Form DEA-106, Report of Theft or Loss of Controlled Substances

ATTACHMENTS

Attachment A – Controlled Drug Count Sheet

Attachment B – Controlled Substances Discrepancy Resolution Report (DRR)

RELATED POLICIES

Access to Medication Storage Areas

Pyxis MedStation Controlled Substances

Pyxis MedStation Downtime

Medication Disposal and Destruction

Patients’ Own Medications

Unusual Occurrence Incident Report

REVISION RECORD

DATE	VERSION	REVISION DESCRIPTION
DRAFT	3.0	<ul style="list-style-type: none"> Updated to reflect implementation of the Department Pharmacy and Pyxis MedStation for managing PHF medications.

Culturally and Linguistically Competent Policies

The Department of Behavioral Wellness is committed to the tenets of cultural competency and understands that culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse individuals. All policies and procedures are intended to reflect the integration of diversity and cultural literacy throughout the Department. To the fullest extent possible, information, services and treatments will be provided (in verbal and/or written form) in the individual’s preferred language or mode of communication (i.e. assistive devices for blind/deaf).

PHF CONTROLLED DRUG COUNT SHEET

Year _____ Month of _____

Date ___/___/___ Date ___/___/___ Date ___/___/___
7 am _____ & _____ & _____ 7 am _____ & _____ & _____ 7 am _____ & _____ & _____

7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____

Date ___/___/___ Date ___/___/___ Date ___/___/___
7 am _____ & _____ & _____ 7 am _____ & _____ & _____ 7 am _____ & _____ & _____

7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____

Date ___/___/___ Date ___/___/___ Date ___/___/___
7 am _____ & _____ & _____ 7 am _____ & _____ & _____ 7 am _____ & _____ & _____

7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____

Date ___/___/___ Date ___/___/___ Date ___/___/___
7 am _____ & _____ & _____ 7 am _____ & _____ & _____ 7 am _____ & _____ & _____

7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____

Date ___/___/___ Date ___/___/___ Date ___/___/___
7 am _____ & _____ & _____ 7 am _____ & _____ & _____ 7 am _____ & _____ & _____

7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____ 7 pm _____ & _____ & _____

INSTRUCTIONS

1. Controlled drugs are counted twice daily, at change of shift (7am & 7pm).
2. Count is performed by one day staff person and one night staff person and the oncoming Team Lead verify.
3. If count is incorrect, do not sign count. Instead, document problem on reverse side, and notify supervisor.
4. Count sheets remain in book until book is thinned. Old copies, removed during thinning, are routed to supervisor for archiving.

(Sign when correct)



Controlled Substances Discrepancy Resolution Report (DRR)

*Attach all hard copy documentation

Tracking Number:		Resolved <input type="checkbox"/>	Unresolved <input type="checkbox"/>
Site:		Date:	
Report Completed By:		Signature 1:	Signature 2:
Drug Name:	Drug Strength:	Formulation:	
Initial Physical Count (A):	Initial Computer Count (B):	Discrepancy (=A-B):	

Resolution Description (Check One):		
Arithmetic error <input type="checkbox"/>	Receiving error <input type="checkbox"/>	Computer Entering Error <input type="checkbox"/>
Dispensing error <input type="checkbox"/>	Count Error <input type="checkbox"/>	Other <input type="checkbox"/>
Explanation of Error:		
Count adjusted (Check One):		
Computer <input type="checkbox"/>	Manual Log <input type="checkbox"/>	

Unresolved

Date Manager Notified: _____

Manager Investigations		
Discrepancy Resolved (Check One):	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Explanation:		
Date Pharmacy Management Notified of Unresolved Discrepancy:		
Incident Report Completed (Check One):	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Date Loss/Theft Report Completed:		
Manager's signature:		

