STANDARD OPERATING PROCEDURE

Controlled Substances Handling SOP

Document no.	SOP-PHA-002
Revision	1.0
Owner	Pharmacist in Charge
Effective date	September 15, 2026
Review cycle	Every 6 months

1. Purpose

To handle controlled substances so that receipt, storage, dispensing and destruction are documented, balances are reconciled, and any loss or discrepancy is caught and reported quickly.

2. Scope

Applies to all scheduled controlled substances received, stored, dispensed and returned by the pharmacy. Follow your local law and the pharmacist in charge's policy for exact recordkeeping requirements.

Definitions

Perpetual inventory	A running, transaction-by-transaction balance of a controlled substance maintained alongside the physical stock.
Two-person verification	A check where a second authorized staff member independently confirms a count or transaction before it is finalized.
Diversion	The unauthorized removal or misuse of a controlled substance from legitimate pharmacy channels.

3. Responsibilities

Pharmacist	Performs final checks on controlled substance dispensing and daily balance reconciliation.
Pharmacy Technician	Assists with receiving counts, shelving and pulling stock under pharmacist oversight.
Pharmacist in Charge	Approves vault access, investigates discrepancies and reports losses as required by law.
Delivery Driver	Delivers wholesaler shipments and obtains signature confirmation for controlled substance deliveries.

RACI matrix

Activity	Pharmacist	Pharmacy Technician	Pharmacist in Charge	Delivery Driver
Receive and count controlled substance shipment	A	R	I	C
Dispense a controlled substance prescription	R/A	C	I	-
Reconcile daily perpetual	R/A	C	I	-

Activity	Pharmacist	Pharmacy Technician	Pharmacist in Charge	Delivery Driver
inventory				
Investigate and report a discrepancy	R	I	A	-
Approve vault or safe access	C	I	A	-

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- Locked vault or safe rated for controlled substance storage
- Perpetual inventory log or software module
- Official controlled substance order forms
- Two-person count verification sheet
- Discrepancy and loss report forms

Personal protective equipment

- Disposable nitrile gloves

5. Procedure

Step	Task	Owner	Done
5.1	**Verify the shipment against the order** On delivery, compare the wholesaler's shipment to the original order form and packing slip, checking drug names, strengths and quantities before signing for receipt.	Pharmacist	☐
5.2	**Perform a two-person receiving count** Count each controlled substance item with a second authorized staff member present, and have both people sign the receiving count verification sheet. **Checkpoint:** The receiving count is signed by two authorized staff members before stock is shelved.	Pharmacy Technician	☐
5.3	**Log the shipment into the perpetual inventory** Enter the received quantity into the perpetual inventory log or software immediately after the count, updating the running balance for each item.	Pharmacist	☐
5.4	**Store in the vault or safe** Place controlled substances in the locked vault or safe designated for that schedule, restricting the combination or key to authorized staff only.	Pharmacy Technician	☐
5.5	**Verify the prescription before dispensing** Check the prescription for validity, prescriber authority and any red flags for diversion, such as early refill requests or unusual quantities, before filling. **Warning:** Do not dispense a controlled substance prescription that raises unresolved diversion concerns without further verification.	Pharmacist	☐
5.6	**Dispense with technician assistance** Have the technician pull and count the medication under direct pharmacist oversight, then hand off for the pharmacist's final check.	Pharmacy Technician	☐

Step	Task	Owner	Done
5.7	**Record the dispensing transaction** Log the dispensed quantity in the perpetual inventory immediately, updating the running balance for that item and patient.	Pharmacist	☐
5.8	**Reconcile the daily balance** At the end of each day, compare the physical count in the vault or safe against the perpetual inventory balance for each controlled substance. **Checkpoint:** The physical count matches the perpetual inventory balance before the reconciliation is signed off.	Pharmacist	☐
5.9	**Investigate any discrepancy immediately** If the physical count does not match the perpetual inventory, recount immediately, review recent transactions, and document the investigation the same day.	Pharmacist	☐
5.10	**Report loss or theft** Report any confirmed loss, theft or unresolved discrepancy to the pharmacist in charge and to the appropriate authorities as required by local law.	Pharmacist in Charge	☐
5.11	**Return expired or unused stock** Segregate expired or unused controlled substances for return through an authorized reverse distributor, following the expired medication disposal SOP for documentation.	Pharmacist	☐
5.12	**Review vault access periodically** Review the list of staff with vault or safe access on a set schedule, removing access for anyone who has changed roles or left the pharmacy.	Pharmacist in Charge	☐

6. Quality checks

- Every receipt is counted and signed by two authorized staff.
- The perpetual inventory balance matches the physical count at each daily reconciliation.
- Every dispensing transaction is logged the same day it occurs.
- Vault access is limited to staff on the current authorized list.

7. Records

- Perpetual inventory log
- Two-person receiving count sheets
- Daily reconciliation records
- Discrepancy and loss reports

8. KPIs

- Number of unresolved discrepancies per month
- Percentage of daily reconciliations completed on time
- Average time to resolve a flagged discrepancy
- Number of vault access changes reviewed per quarter

9. Common mistakes

- Shelving a controlled substance delivery before completing the two-person count.
- Delaying the perpetual inventory entry until later in the shift.
- Skipping the daily reconciliation on a busy day.
- Leaving vault access unreviewed after staff turnover.

10. Revision history

Revision	Date	Description	Reviewed by
1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

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