

VA NORTHEAST OHIO HEALTHCARE SYSTEM
LOUIS STOKES CLEVELAND DVAMC
MEDICAL RESEARCH SERVICE
SUBCOMMITTEE ON RESEARCH SAFETY POLICY

Effective Date: APRIL 14, 2021

SOP Title: CONTROLLED SUBSTANCE PROGRAM: MEDICAL RESEARCH

SOP Number: SRS--016

SOP Version: .09

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1. **PURPOSE:** To state policy, responsibility, and guidelines for the use of Controlled Substances in Medical Research Service.

2. **POLICY:** To ensure that Controlled Substances, as listed in Title 21 Code of Federal Regulations (CFR) Schedule II-V (1308.12 through 1308.15); 21 CFR 1301; and Title 21 United States Code (U.S.C.) 812 and 827, are received, secured, and usage is properly recorded.

3. **DEFINITIONS:**
 - a. **Controlled Substance** – A drug that has the potential for abuse and for which manufacturing, sale, distribution and use are controlled by regulation. Schedule II substances have the highest risk for abuse and are therefore most stringently controlled. Remaining schedules have less potential for abuse and are therefore progressively less controlled.

 - b. **Pyxis MedStation®** – The Pyxis MedStation® provides secure, automated supply dispensing and gives you the ability to document usage in real-time, which helps to reduce documentation errors.

 - c. **Expiration Dates:**
 - (1) The date in which a Pharmaceutical Company identifies a substance as being past its usefulness. Expired medications should not be administered because potency, sterility and stability cannot be assured. At the time of expiration, the Pyxis MedStation® sends an alert to the Pharmacy Program Specialist, who in turn removes the expired substance from the Pyxis MedStation® and returns it to Pharmacy Service.

(2) Controlled Substances and other multi-dose vials must be dated with a 28-day expiration date after the manufacturer's seal has been broken. Controlled substance mixtures (cocktails) expire 28 days after preparation. The expiration process for a cocktail is the same as with substances in their original containers; the Pyxis MedStation® sends an alert to the Pharmacy Program Specialist, who in turn removes the expired cocktail from the Pyxis MedStation® and returns it to Pharmacy Service.

- d. "0" Balance – A controlled substance has been completely used.
- e. Discrepancies – When requirements for work with and/or storage of controlled substances is inconsistent with standard procedures detailed in section 4 of this policy.
- f. Controlled Substance Inspectors – Two Inspecting Officials, i.e. from Police Service, Pharmacy Service, or the Director's Office, who conduct random, unannounced inspections as assigned by the Controlled Substance Coordinator/Director's Office.
- g. Cocktail – A controlled substance mixture.
- h. Laboratory Log-Book – A log-book that records controlled substance usage. This entry must include the common name of the drug, the date used, the amount used, the procedure, and the person who used this drug in the procedure. Cocktails that contain a controlled substance must also be logged appropriately in this log-book.

4. PROCEDURE:

- a. Controlled Substance Authorization: Only persons authorized/trained by the Pharmacy Program Specialist/Pharmacy Service are authorized to access the Pyxis MedStation®.
- b. Dispensing of Controlled Substances: The Pharmacy Program Specialist/Pharmacy Service dispenses all controlled substances into the Pyxis MedStation®. Dates of dispense and a corresponding six-digit Identification number are recorded in the Pharmacy Service's VISTA dispensing menu.
- c. Controlled Substances cannot be stored outside the Pyxis MedStation®. Any controlled substance withdrawal must be used that same day; any remaining drug must be discarded (wasted), as noted in part "e" below.
- d. Each withdrawal of a controlled substance is recorded in the Pyxis MedStation®; this includes the amount withdrawn from the original vial, to make a controlled

substance cocktail, or a withdrawal from a controlled substance cocktail. This information includes the date, time, dose, balance, and person withdrawing the dose.

- e. Any drug withdrawn, but not used, must be discarded (wasted). When wasted, the drug must be witnessed by two authorized personnel; this information must be documented in the Pyxis MedStation® to account for the amount not used. This process aids in accounting for controlled substances.
- f. Completion of Controlled Substance: When a controlled substance has a “0” balance, and there is no drug physically remaining, an alert is sent to Pharmacy Service for replenishment.
- g. Security of Controlled Substances: The Pyxis MedStation® is an automated medication dispensing system that is accessed by both a user ID and fingerprint recognition.

Note: There is no mechanism in place within the Pyxis MedStation® to limit personnel the ability to only access the controlled drugs that they are authorized to use. Anyone who has access to the Pyxis MedStation® has access to all the controlled drugs within it. When trained by the Pharmacy Program Specialist, personnel are instructed to only obtain controlled substances by selecting the name of their Principal Investigator (PI) and the controlled substances that they are approved to use.

In the event of a discrepancy, e.g. removal of a controlled substance from the Pyxis MedStation®, under the wrong PI, the Controlled Substance Inspectors will be able to identify who removed the drug by reviewing the Pyxis MedStation® activity record. With this information, the inspection team will be able to work with the employee and the employee’s PI to resolve this issue.

- h. Inspection of Controlled Substances: Controlled Substance Inspectors conduct monthly inspections of the Pyxis MedStation® system and the Laboratory Log Books. The Laboratory Log books must reflect what was removed from the Pyxis MedStation® and be readily available.

5. RESPONSIBILITIES:

- a. Associate Chief of Staff/Research (ACOS/Research):

(1) Discrepancies are reviewed and resolved by the ACOS/Research.

b. Pharmacy Service:

- (1) Dispenses controlled substances into the Pyxis MedStation®.
- (2) Disposes unused and/or outdated controlled substances.
- (3) Maintains the Pyxis MedStation®.

c. Laboratory Staff:

- (1) Obtain controlled substances by selecting the name of their Principal Investigator (PI) and the controlled substances that they are approved to use.
- (2) Notes an expiration date on vials containing controlled substance cocktails. The expiration date for a controlled substance cocktail is 28 days after preparation but should not exceed the manufacturer's expiration date noted on the original vial.
- (3) Reports irregularities (theft, inappropriate diversion of drugs, etc.) to the Pharmacy Program Specialist/Pharmacy Service.

d. Controlled Substance Inspectors:

- (1) Inspect the Pyxis MedStation® and Laboratory Log-Books.
- (2) Ensure that discrepancies noted during an inspection are immediately investigated and reported in accordance with hospital procedures.
- (3) Provide a report to the Controlled Substance Coordinator, who will make a report of findings to the Facility Director or National CMOP Director for appropriate action.

e. Controlled Substance Coordinator (CSC)

- (1) Oversees random inspections of controlled substances and controlled substances records.
- (2) Ensures that Discrepancies are reviewed and resolved by the Associate Chief of Staff/Research (ACOS).

6. REFERENCES: VHA Handbook 1108.1 “Controlled Substances (Pharmacy Stock)”; VHA Handbook 1108.2 “Inspection of Controlled Substances”; and Medical Center Policy 119-003, Controlled Substances.

7. RESCISSION: SRS Policy 016 dated April 14, 2021, Controlled Substance Program: Medical Research. The rescission date for this policy is April 8, 2026.

8. FOLLOW-UP RESPONSIBILITY: Research Safety Coordinator.