CONTROLLED SUBSTANCES AND DIVERSION

CFR Title 21, Section 812 defines the Schedules of Controlled Substances.

The Controlled Substances Act (CSA) was enacted into law as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. These regulations are designed to ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes, and to deter the diversion of controlled substances to illegal purposes. The Drug Enforcement Administration (DEA) is the lead Federal Law Enforcement Agency charged with enforcing the CSA. The CSA places all substances that are regulated into one of five schedules. A substance scheduling is based on one of three factors:

1. The substance’s medicinal value
2. The substance’s possible harmfulness to human health
3. The substance’s potential for abuse or addiction.

Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous drugs.

CONTROLLED SUBSTANCE EXAMPLES

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Description</th>
<th>Examples</th>
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<tbody>
<tr>
<td><strong>Schedule I (CI)</strong></td>
<td>No accepted medical use in the U.S., are not accepted as safe for use under medical supervision, and have a high abuse potential</td>
<td>heroin, marijuana, LSD, peyote, mescaline, ecstasy, gamma hydroxybutyric acid (GHB)</td>
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<td><strong>Schedule II (CII)</strong></td>
<td>A high abuse potential with severe psychological or physical dependence, but have accepted medical use in the U.S.</td>
<td>morphine, codeine, hydromorphone (Dilaudid ®), methadone, meperidine (Demerol ®), amphetamine (Dexedrine ®), methylenidate (Ritalin ®, Concerta ®), fentanyl (Sublimaze ®), dextroamphetamine/amphetamine (Adderall ®)</td>
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<td><strong>Schedule III (CIII)</strong></td>
<td>May lead to moderate or low physical dependence or high psychological dependence; are less likely to be abused than drugs categorized as Schedule I or Schedule II and have accepted medical use in the U.S.</td>
<td>drugs containing limited quantities of certain narcotic drugs (Lortab ®, Vicodan ®) and other non-narcotic drugs such as butabarbital (Butisol ®), butalbital and testosterone</td>
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<tr>
<td><strong>Schedule IV (CIV)</strong></td>
<td>May lead to limited psychological and/or physical dependence; have a relatively low potential for abuse and have accepted medical use in the U.S.</td>
<td>phenobarbital, choral hydrate, chlordiazepoxide (Librium ®), diazepam (Valium ®), oxazepam (Serax ®), lorazepam (Ativan ®), alprazolam (Xanax ®), temazepam (Restoril ®), pentazocine (Talwin ®)</td>
</tr>
<tr>
<td><strong>Schedule V (CV)</strong></td>
<td>Are less likely to cause psychological and/or physical dependence than drugs in any other Schedule; have a low potential for abuse and have accepted medical use in the U.S.</td>
<td>Often available without a prescription and generally limited to small quantities or codeine in cough syrups.</td>
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Your local facility may designate additional high-value drugs or drugs at high-risk for diversion to the Controlled Substance Inspection Program.

We inventory to validate the accuracy of inventories. However, diversion could have still occurred due to less obvious diversion techniques such as replacing liquids with saline or doses with similar looking...
drugs; or due to shorting quantities given to patients (e.g. half or incomplete doses dispensed to an inpatient or clinic patient, shorted doses provided via mail or pharmacy pickup).

There are multiple situations where physical quantities are accurate and diversion could still have occurred. Remember if a person wants to divert, he or she may go to extraordinary measures to conceal the diversion.

All Medical Center employees are responsible for reporting any suspected theft, diversion, or suspicious loss of drugs immediately (the same workday) to their respective supervisor/designee.
CONTROLLED SUBSTANCE INSPECTOR TIPS

ROLE OF THE CONTROLLED SUBSTANCE INSPECTOR

Consolidated Mail Outpatient Pharmacy (CMOP) pharmacists who inspect have no connection to the CS program, but do dispense non-controlled drugs.

All persons that do not have involvement in drug procurement, prescribing, dispensing, or administration can serve as CSIs.

A CSI cannot inspect any area in consecutive months. If a CSC assigns you to inspect the same area in consecutive months, inform him or her that of the scheduling conflict.

You must never schedule your inspections. Inspections must be random and unannounced. You must complete all assigned inspections in a timely fashion, as assigned, before the end of the month. Once you arrive to an inspection area and announce your inspection, you must complete the inspection before you leave.

If there is an unresolved discrepancy, you will follow local guidelines for whom to notify, in what order, and the requisite timeframe for doing so. Those personnel will be responsible for any further actions.

Your CSC may be able to provide insight as to times of high-volume when you might want to avoid inspecting a specific area. The staff does not have to know that you are intentionally avoiding inspecting during those times.

Someone being disrespectful is inappropriate behavior. While complaining and being in a rush can describe difficult personnel, inappropriate behaviors are unacceptable and not to be tolerated.

TIPS FOR A SUCCESSFUL INSPECTION

Professional persistence is the key! You are the inspector. This is your assigned duty. It’s all right to sound like a broken record. Arm yourself with the following phrases and be prepared to use them repeatedly:

- I am required to do this. I cannot leave until it is completed.
- We must complete this mandatory inspection.
- This random, unannounced inspection is a Director’s program.
- The inspection program is supported by the Director.
- The Director assigned me to perform this mandatory inspection. Unless there is an acute emergency, this inspection must be completed now.
- I appreciate you are busy and performing important work. However, this is a mandated program and I must complete the inspection once I announce my arrival.
COUNTING PHARMACEUTICALS

The working inventory of controlled substances must be stored in a locked cabinet or secured cart with electronic access, or commercial automated dispensing system; it must not be dispersed with general pharmacy inventory.

Inspectors are required to count open bottles containing controlled substances and those with tape put on by pharmacy showing the number of pills in the bottle.

A sealed container for inspection purposes is a container that has the original manufacturer seal intact.

A damaged seal or a seal applied by a member of the pharmacy requires the inspector to open the seal to count the items individually.

When measuring liquids use a cylinder size as close to the quantity being measured as possible, read the bottom of the curve, and limit the amount of times the drug is transferred due to expected loss.

When reviewing CS prescriptions, strength in metric dosage is required; as directed or as needed (prn) are not acceptable; only one medication may be prescribed on each VA Form 10-2577F; and the use of a pre-signed prescription form is not authorized.

Prescription limitations for Schedule II controlled substances require prescriptions be written and dispensed in 30-day quantities or less and refills are prohibited.

The only time a CSI is required to witness resolution of a discrepancy is when the discrepancy was created by the inspector or assigned counting assistant during the count.

Include both resolved and unresolved discrepancy information in your report to the CSC.
CONTROLLED SUBSTANCE INSPECTOR TIPS

AUTOMATED DISPENSING EQUIPMENT

If an automated dispensing machine malfunctions, contact the appropriate responsible authority. Do not allow these impediments to prevent you from completing your inspection.

An auditor login must be used in conjunction with a staff member from the area that is being inspected (e.g. pharmacy employee, nurse, researcher, dental staff, etc.) access code to open every bin on the machine for a physical count. No two inspectors or combination of inspector and coordinator are allowed to count an automated dispensing machine without a staff member from the appropriate area present.

When inspecting an automated machine, you will be required to reconcile one day’s dispensing activity from pharmacy to each area that has automated equipment. Your CSC will provide you with clear instructions on how and where you get the reports to validate dispensing activity. You should ensure one day dispensing from pharmacy is shown as being received into the machine on the reports you are provided.

Dispensing activities chosen for validation do not have to be from the day you conduct the inspection. Ensure you know how to obtain the report that shows what was removed from the machine to be administered to a patient so that you can validate the required number of orders.
CONTROLLED SUBSTANCE INSPECTOR TIPS

INSPECT THE PHARMACY

Ensure you complete all the required elements of a pharmacy inspection:

1. Physical Count; drugs may be stored in:
   A. Outpatient Controlled Substance Vault
   B. Inpatient Controlled Substance Vault
   C. Pharmacy working stock locked cabinet
   D. Automated dispensing device
   E. VHA All Hazards/Emergency Drug Cache

2. VHA All Hazards/Emergency Drug Cache
   A. Verify locks are intact and number is unchanged

3. Drugs Held for Destruction
   A. Verify destruction done at least quarterly
   B. Perform audit trail of 10 drugs if a destruction was conducted since the last inspection

4. Drug Procurement, Invoice Review

5. Review inventory records and verify pharmacy staff inventory all stock of controlled substances every 72 hours as required

6. Prescription Pad Inventory

7. CII Outpatient Prescription Review

In the outpatient pharmacy, the CSI must randomly select and verify that there is a hard copy prescription (written "wet signature" prescription) for 10% (or maximum of 50) of the Schedule II controlled substances dispensed. You should also verify the patient name, drug, strength and quantity on the report matches the information on the prescription.

The Chief of Pharmacy, or designee, and CSI must perform a complete physical count for all line items in the pharmacy during the first month of each quarter.

The Chief of Pharmacy, or designee, and CSI must perform a random physical count of a minimum of 10 percent (or maximum of 50) of the line items during the other 2nd and 3rd months of the quarter.

100% of invoices must be verified against the Pharmacy Drug Receipt History Report in VistA and the invoices should be obtained from Logistics not the pharmacy.

Drugs held for destruction in the pharmacy must be in a sealed evidence bag with the date, name, and quantity of the controlled substance written on the evidence bag and stored in the vault.

The Pharmacy should never have a box or tote of unprocessed medications (expired stock or patient medications). Pharmacy should log items on the destruction report and place in a sealed evidence bag as soon as possible. Deviations from this process should be noted in your report.
Once a quarter the Emergency Cache totes containing controlled substances must be opened (seal broken) and contents physically counted as part of the inspection. A new seal is then applied and recorded.

The portion of Emergency Cache inventory that is contained in a bin with an intact seal does not need to be individually counted in non-complete physical count month inspections (e.g., second and third month of the quarter), but can be accounted for by verifying that their outer seals are intact and the lock number is unchanged from the last inspection.

Pharmacies open 5 days per week must complete two inventory checks weekly while pharmacies open 7 days per week must complete three inventory checks weekly.

VHA All Hazards Cache controlled substance inventory must be reviewed every 72 hours (if the pharmacy has a waiver from Pharmacy Benefits Management Services the inventory may be reviewed weekly).
CONTROLLED SUBSTANCE INSPECTOR TIPS

INPATIENT UNITS AND CLINICS

The CSI must perform a complete physical count on all unit and clinic areas during the first month of each quarter. A random physical count of a minimum of 10 line items must take place during the other 2 months of the quarter.

In the inpatient or clinic setting, the CSI must perform a review of five randomly selected dispensing activities and verify that there is a provider order and documentation of administration in the patient’s medical record to support each dispensing activity.

On a unit with less than five dispensing activities, a minimum of two orders will be reviewed. Inspectors review doctor orders to validate medication orders for a patient to verify the drugs signed out were actually to fulfill doctor’s orders, not diversion.

You should choose the five patients randomly from the Green Sheet (s) or automated dispensing device report. Do not ask any nurse for names. Time frame is the entire month; therefore, inpatient units should generally have five activities.

CSIs pull five patient records to validate the doctor orders match the dispensing record and that the patient received the drug and strength that was removed from the machine within a reasonable timeframe from when it was removed.
INSPECT THE CONSOLIDATED MAIL OUTPATIENT PHARMACY

The Consolidated Mail Outpatient Pharmacy (CMOP) facility uses an electronic CS perpetual inventory to track their daily dispensing activity. The Green Sheet and Form 10-2638 are used for other facilities and form 10-2577f is a hardcopy prescription also not used in a CMOP.

Verifying that Drugs Held for Destruction are stored with usable drugs is not a responsibility of the CSI. However, Drugs Held for Destruction should have a corresponding deduction from inventory.

Responsibilities of CSI who inspect Consolidated Mail Outpatient Pharmacy (CMOP) facilities include:

A. Verify that review of externally reported quantity and mail delivery errors is performed monthly.
B. Verify that controlled substances received were placed into inventory.
C. Count physical inventory and reconcile to a computerized inventory report.

In the Consolidated Mail Outpatient Pharmacy (CMOP), the CSI should validate Drugs Held for Destruction have a corresponding deduction from inventory.
The Medical Center Director must authorize a designated provider to have overall responsibility to ensure the security, handling and storage requirements for controlled substances are followed in research. You will be required to validate this authorization during your inspection. Accomplish by asking to see the authorization and inspecting it to ensure it is still current (date and provider).

In research, you will always count 100% of all stored controlled substances every month. There is no random counting of a lesser percentage on the 2nd and 3rd months of a quarter.

VA Form 10-2638 must accompany each container of drugs issued.

When inventory for a specific VA Form 2638 is depleted, that form is zeroed out, signed, dated by the designated provider, and returned to the Pharmacy within 72 hours.

All controlled substances in research must have been ordered and dispensed from the VA Pharmacy. Researchers may not bring in controlled substances from other facilities they may work at (e.g. local University).

VA Handbook 0730 Security and Law Enforcement provides regulation as to the security of Schedule I through V Controlled Substances within VA facilities. If the research facility is not using an automated dispensing device, they must store all controlled substances under double lock. Controlled Substances should not be stored in Researcher’s desk or file cabinets. If controlled substances are not secured under double lock you should report this to the CSC and Chief of Pharmacy.
Inspectors have three duties in reporting and documenting inspection findings.

1. Report any discrepancies to the person in charge of the area you inspected. Make a verbal report of any discrepancies you found before you leave the area.
2. Report any discrepancies to the CSC immediately upon completion of the inspection.
3. Complete the necessary paperwork to document and report your findings.

When reporting and documenting inspection findings, the CSI reports to your CSC, the CSC may decide the situation warrants contacting the VA Police to report unresolved discrepancies.

If, while validating dispensing activities during inspection of an inpatient unit, you find an administration activity for a controlled substance without a corresponding doctor's order in the patient's medical record, document the issue as a discrepancy in your report, and include any additional information the nurse tells you. Do this even if the nurse provides what seems like a plausible explanation for the missing documentation. Your role is to report the discrepancy, not to assume if someone diverted drugs or suggest who may have done so.