

# Controlled Substances

## Frequently Asked Questions

April 4, 2005

1. **Question:** Is there a requirement to have an alternative Controlled Substance Coordinator as recommended by some SOARS team members and IG CAP visits?

**Answer:** The medical center Director is responsible to name the Controlled substance Coordinator. If the scope of this job or the number of locations impact the ability for a single person to oversee this program, it may be advisable (but not REQUIRED) to name an alternate Controlled Substances Coordinator.

2. **Question:** How frequently should Research be expected to do inventory or the equivalent of shift counts during a month?

**Answer:** With the exception of the weekly automation equipment quality control inventory, there is no specific VHA policy guidance regarding shift counts in the pharmacy, research, and nursing (patient care) areas. VHA policy only requires that research areas maintain Controlled Substance accountability sheets (green sheets) AND make all controlled substance storage areas accessible for monthly unannounced inspections. There is no VHA policy requirement for interim (daily, weekly, etc.) inventory counts by Research personnel or other hospital personnel beyond the monthly unannounced inspection.

3. **Question:** Can an inspector complete more than 6 inspections in per year?

**Answer:** A controlled substance inspector can complete one inspection per month for the entire 3 year term of office as long as they are not assigned to inspect the same location 2 months consecutively. There are too few qualified inspectors to limit the number of inspections to 6 per person per year.

4. **Question:** What is meant by validating all transfers during the monthly inspection?

**Answer:** Each site should be using the VISTA controlled substance package with or without dispensing automation. Verification of a transfer is a comparison of the electronic record to show that a removal transaction at one location results in a new addition to a different receiving location.

5. **Question:** Why do we need to do a weekly inventory of automated dispensing devices, especially if the devices are under the control of pharmacy?

**Answer:** Traditionally, “change of shift counts” were initiated by nursing to indicate a change of responsibility for the controlled substances on that ward. The use of automated dispensing devices has been suggested as justification to eliminate the need for the

change of shift count. Elimination of shift counts for automated dispensing devices is not possible at this time due to a variety of factors, including:

- Some devices do not permit acceptable verification. For example, older devices with Matrix drawers allow access to the entire package
- Not all devices are under the control of the pharmacy departments

VHA will revisit the continued requirement for shift counts on automated dispensing devices as the technology continues to evolve.

6. **Question:** Why does Nursing have to verify what a pharmacy tech puts into the automated dispensing equipment?

**Answer:** The entry of new products into the dispensing devices is required to document a change of possession from one individual / service to another. You may use automated reports from VISTA and the Access Control Devices to verify the Inventory of items added.

7. **Question:** Why does a pharmacist have to dispense take home doses in the Methadone Maintenance Program when they use an automated dispenser?

**Answer:** Under Federal law, only pharmacists and physicians may dispense medication. Not all Opioid Treatment Programs (OTP) employ a pharmacist for dispensing. According to the Nursing Practice Acts in most states, the act of providing more than a single medication dose for immediate use by a patient is considered dispensing, and is therefore prohibited. To prevent putting VA nurses in conflict with their State Boards of Nursing regarding the prohibition on dispensing, in VA pharmacists are required to dispense multiple take home medication doses.

8. **Question:** When should a balance adjustment be made (daily, every 72 hours, or at the monthly inspection)?

**Answer:** A Balance adjustment can be done any time a discrepancy is identified. Many manufacturers' bottles contain more or less than the stated amount due to the FDA allowed method of filling by weight. Miscounts or items dropped on the floor in the process of dispensing should be administratively adjusted each time they are identified. These balance adjustments will be reviewed during the Monthly Inspection process for any unusual trends. Any unusual trend is to be reported to Security, the CSC, the OIG, and VA Central Office Pharmacy office (ATTN: Jeff Ramirez) per Handbook 1108.1.