

Countable Controlled Substances

What are they and why do we need to count them so carefully every day?

Objectives:

1. Participants will identify the reason for careful counting of Countable Controlled Substances.
2. Participants will recognize how to maintain security for Countable Controlled Substances.
3. Participants will demonstrate an accurate 2 person count.
4. Participants will state the responsibility of the MAP Certified staff assigned to administer medications in maintaining the security of Countable Controlled Substances.

Content:

Historical Background

In 1970, the Federal Government passed the 'Comprehensive Drug Abuse Prevention and Control Act'. In this Act, medication and other substances are cataloged in one of five lists called Schedules. The Schedules are based on the substance's use as a medicine and the potential for abuse or addiction.

Massachusetts General Laws Chapter 94C indicates the establishment by regulation of six schedules of controlled substances. Massachusetts incorporates the five Schedules cataloged under the 'Federal Comprehensive Drug Abuse Prevention and Control Act of 1970' along with a 'sixth' Schedule (Schedule VI).

In Massachusetts, all medications referenced in Schedule II – VI are categorized as Controlled Substances. In addition, the Medication Administration Program (MAP) further categorized those medications referenced in Schedule II-V as 'Countable' Controlled Substances.

Schedule I-VI Controlled Substances

- **Schedule I Controlled Substances:** Substances in this Schedule have a high potential for abuse and have no currently accepted medical use in treatment in the United States. Examples: LSD and Heroin
- **Schedule II Controlled Substances:** Substances in this Schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples: OxyContin and Demerol
- **Schedule III Controlled Substances:** Substances in this Schedule have a potential for abuse less than substances in schedules I or II and

abuse may lead to moderate or low physical dependence or high psychological dependence. Examples: Vicodin and Tylenol with Codeine (containing not more than 90 milligrams of codeine per dosage unit)

- **Schedule IV Controlled Substances:** Substances in this Schedule have a low potential for abuse relative to substances in Schedule III. Examples: Valium and Ativan.
- **Schedule V Controlled Substances:** Substances in this Schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Examples: Robitussin AC and Phenergan with Codeine (preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams).
- **Schedule VI:** Substances in this Schedule include all prescription drugs not included in the first five Schedules. Example: Penicillin and Dilantin.

The Scheduling of Controlled Substances has changed throughout the years. Since the establishment of the Federal 'Comprehensive Drug Abuse Prevention and Control Act of 1970', approximately 160 substances have been added, removed, or transferred from one Schedule to another (within Schedules I through V).

Record Keeping, Security, and Inventory Requirements

All DPH MAP Registered Sites must conform to the record-keeping and inventory requirements of the Federal 'Comprehensive Drug Abuse Prevention and Control Act of 1970', any other Massachusetts rules or regulations, and policies within the MAP Policy Manual. Section 10 of the MAP Policy Manual contains policies on Medication Security and Record Keeping of Controlled Substances.

Examples of procedures to follow to ensure DPH MAP Registered sites conform to requirements.

1. Site must limit access to the medication storage area.
 - a. A Certified staff is assigned the task of medication administration at the Registered Site by the Site Supervisor (or designee)
2. The Certified staff who is assigned to give medications for the shift is responsible for the inventory (supply) of Countable Controlled Substances during their assigned shift.
 - a. Assigned Certified staff must count the Countable Controlled Substances at the beginning and end of assignment and document within the Countable Controlled Substance Book if a 'Countable' Controlled Substance has been administered.

3. Assigned Certified staff must make sure that all Controlled Substances are locked and all Countable Controlled Substances (Schedules II-V) are double locked.
4. The keys to the Medication Storage Area and the Countable Controlled Substances Storage Area must be with the assigned Certified Staff (on their person) during their entire assignment (while working at the site).
 - a. A neck/pocket lanyard (bungee-cord, etc.) may be used for this purpose.
5. Countable Controlled Substances must be received from the Pharmacy in Tamper-resistant packaging.
 - a. Examples of Tamper-Resistant Packaging include Blister Packs, Unit Dose Bottles, etc.
6. Whenever the assigned Certified staff (medication administrator) changes a Countable Controlled Substance count must be done and the control of the medication key passed from the off-going Certified staff to the on-coming Certified staff.
 - a. The keys should be passed person to person and the count should be done 'shoulder to shoulder'.
7. Assigned Certified staff must track all 'Countable' Controlled Substances in the Countable Controlled Substance Book. Examples to assist in proper tracking:
 - a. Assigned Certified staff, who receives the medication from the pharmacy, should add the medication to the Countable Controlled Substance Book Index and the next available 'Countable' entry page.
 - b. The index must be kept accurate and up to date to include each 'Countable' medication, its strength, and the current page listing.
 - i. The Site Supervisor is responsible for removing a medication from the Book's Index page and ensuring its accuracy.
 1. The Service Provider can establish a back-up for the Site Supervisor (e.g., Site Supervisor's Manager) in the event the Site Supervisor is not accessible.
 - c. Assigned Certified Staff should document when a 'Countable' has been given and verify the number of pills that are left.
 - d. When transferring to a new 'Countable' entry page, assigned Certified staff should document the new page the 'Countable' is moving to, and the number of pills being transferred. This information should be verified with another Certified staff (both people should be MAP Certified). Certified staff involved in the transfer should sign their name in the designated area confirming the transfer.
 - i. The Index should be updated whenever a medication has been transferred to a new page in the Book.

- e. When a medication is discontinued, the assigned Certified staff and the Site Supervisor must (together) ensure that the medication has been rendered unusable and document that information on the bottom of the 'Countable' entry page. A notation should be written indicating the date/time, number of pills rendered unusable, and a '0' should be entered in the "Amount left" column. After the page has been 'zero-out' the assigned Certified staff and the Site Supervisor should sign (with legal signature) in the designated area.
 - i. When the page has been zero-out, the Site Supervisor should also remove the page from count and update the index.
 - 1. The Site Supervisor must remove the 'Countable' from the Book's Index page by signing in the 'Staff Responsible' for Removing Medication from Count column.
 - a. After removing the 'Countable' from the Book's Index, the Site Supervisor may highlight that entry using a yellow highlighter.
 - b. When an entry has been removed from the Book's Index by the Supervisor, Certified staff will no longer have to turn to that referenced page when performing Countable Controlled Substance Count.
 - ii. The 'Countable' disposal information must also be documented on the 'Controlled Substance Disposal Record'.
- f. All Countable Controlled Substances must be 'counted' whenever the control of the medication storage area keys is passed.
 - i. For example at the beginning and end of the shift/assignment
 - ii. When two Certified staff are available there must always be a two person count (2 people counting together)
 - 1. If there is no one else available, a single person count may be done. Indicate on the count signature page, that a 'single person count' was done and no witness was available.
 - 2. Conducting a two-person count at least once in twenty four hours is an exception to the MAP Policy. This exception should only be followed at those sites where there is only one assigned Certified staff and the only time there may be overlap (of Certified staff) is once in twenty four hours (possibly at 11 PM)
- g. If the count is incorrect, a supervisor must be notified immediately. If it was determine that there was a drug loss, tampering, etc. the

DPH Drug Incident Report must be completed and faxed to (617-524-8062). The form should be faxed within one business day of discovery.

- h. If there will be no Certified staff in the home during the day, the keys may be locked in a combination realtor-type locked box. A count must be done by assigned Certified staff who will be putting the keys in the locked key box and by assigned Certified staff who has removed the keys from the locked box.
 - i. Only currently MAP Certified staff should know the code to the key box.

Frequently Asked Questions

How would Certified staff know which medications are 'Countable' Controlled Substances (Schedules II-V)?

Ask the consulting pharmacist/pharmacy to place an identifier (e.g., 'C' or 'N') on the pharmacy label indicating that the medication is a 'Countable' Controlled Substance and must be 'counted' and added to the Countable Controlled Substance Book.

Why is counting and recording so important?

To help protect the safety of individuals living at the DPH MAP Registered Site.

To help protect Certified staff from being accused of mishandling or misusing Controlled Substances.

To assist Certified staff in adhering to applicable laws, regulations, and policies (when Controlled Substances are stored at the DPH MAP Registered Site)

If Countable Controlled Substances are taken by a Certified staff, an investigation will follow with possible police involvement.

Role Play

The Trainer should demonstrate a two person Countable Controlled Substance Count followed by a return demonstration by each participant.

Additional Exercises

Certified staff can complete Countable Controlled Substances Book Documentation exercise.

Certified staff can complete the Managing Countable Controlled Substances Quiz

Questions/Answers/Wrap Up