**CONTROLLED SUBSTANCE INVENTORY POLICY & PROCEDURE**

**Purpose:**

This Policy and Procedure outlines the Pharmacies requirements for Controlled Substance Inventory.

Controlled substance inventories are an important aspects of the pharmacies DEA program. Inventory maintenance is the key to the loss detection, theft, and diversion of controlled substances.

**Scope:**

This policy and procedure applies to {List all pharmacies under common ownership} and to the associates managing and working in those locations who perform inventory of control substances in compliance with [Title 21 United States Code (21 U.S.C.) 801-971](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html); the DEA regulations Title 21, Code of Federal Regulations [(21 C.F.R.), Parts 1300 to End](http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html); and State regulatory requirements.

**Responsibility:**

It is the responsibility of the Registrant to remain aware and current of laws and regulations affecting the controlled substance inventory process. Registrant can delegate this responsibility to a Pharmacist In Charge (PIC) but remain ultimately responsible for the conduct of the facility.

**DEFINITIONS:**

**Controlled Substances:**  Substances designated as Schedule I-V (C-I, C-II, C-III, C-IV and C-V) according to their medical use, potential for abuse, safety, or dependence liability.

**Inventory**: A complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for Schedule II controlled substances and an estimated count or measure of the contents of a Schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made).

**Inventory Records**: The forms or logs where the results of the inventory have been documented. All inventory records must be maintained at the registered location in a readily retrievable manner for at least 2 years for copying and inspection. In addition, the inventory records of Schedule II controlled substances must be kept separate from all other controlled substances.

**PROCEDURE:**

**General Information and Inventory Requirements**

1. It is the responsibility of each Registrant to list and inventory all controlled substances in stock at the appropriate times.
2. The normal inventory date is May 1st ANNUALLY for ALL controlled substances. Any deviation from the May 1st date of the inventory requires notification of the Drug Enforcement Administration (DEA) of a new "fixed "date and approval by the state Board of Pharmacy.
3. When a medication is added to the controlled substance list, that product will be inventoried on the date the rule becomes effective.
4. Inventory should be conducted before or after open hours and noted on a cover sheet of the physical inventory forms or logs. This information should be date and time stamped with signature of person conducting the inventory. See Attachment: Controlled Substance Inventory Cover Sheet
5. If the inventory is taken during open hours of the Pharmacy, inventory quantities shall be adjusted to reflect actual quantities on hand at either the open or close of business of the date of inventory.
6. CII Inventory: Exact counts shall be made on all CII medications.
7. CIII, CIV, and CV counts may be estimated if bottle size is for 1,000 dosage units or less.
8. In addition to the normal May 1st inventories required, a full inventory of ALL Controlled Substances medications shall be performed:

* Within 10 days of assumption of Pharmacist-in-Charge (PIC) duties;
* Immediately upon change of ownership of the Pharmacy; and
* As part of the procedures for closing the Pharmacy.

1. All losses of controlled substance medications shall be reported as per the DEA and State regulatory requirements.

**Initial Inventory**

1. When issued a DEA registration, a registrant must perform an initial inventory or physical count of all controlled substances in their possession. The Inventory Record must include:

* Controlled Substance Inventory Cover Sheet: See Attachment
  + Name of Pharmacy:
  + Address of Pharmacy:
  + DEA Number of Registrant:
  + Inventory Date:
  + Inventory Time:
  + Before Business Opening:
  + After Business Opening:
  + Names of Persons Conducting Inventory:
  + Signature of Persons Conducting Inventory:
* Inventory Forms or Logs: See Attachment
  + Name of each controlled substance inventoried
  + Finished form of each of the substances (e.g., 5 milligram capsule)
  + The number of dosage units of each finished form in the commercial container (e.g., 500 capsule bottle)
  + The number of commercial containers of each finished form (e.g., two 500 capsule bottles)
  + A count of the substance: If the substance is listed in Schedule II, an exact count or measure of the contents; or if the substance is listed in Schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case, an exact count of the contents is required
  + The signature of the person or persons responsible for taking the inventory

1. If there is no stock of controlled substances on hand, the registrant should make a record showing a zero inventory.
2. If during the inventory process for controlled substances the following are identified, the Pharmacy must follow policies and procedures for transfer or disposal of controlled substances, removal of expired drugs, product recall, and return of a prescription drug or device:

* Unused, unwanted, expired, recalled, damaged, deteriorated, or other quality issue, rendering medication unsafe for use

1. All inventory records must be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection.

**Annual Inventory**

1. Pharmacy will comply with the state legal requirements for inventory of controlled substances.
2. Annual inventory (once per year) requires the same information as the initial inventory (see list above) of all controlled substances on hand.
3. Conducted on May 1st each year before the open of business or after the close of business.
4. Annual Inventory records must be filed and maintained at the registered site in a readily retrievable manner for at least two years or as per state regulation.

**Biennial Inventory**

1. Federal Regulatory Requirement: Biennial Inventory (every 2 years) from the date of the initial inventory,
2. Biennial Inventory requires the same information as the initial inventory (see list above) of all controlled substances on hand.
3. Biennial Inventory may be taken on any date which is within 2 years of the previous inventory date.
4. Biennial Inventory records must be filed and maintained at the registered site in a readily retrievable manner for at least 2 years or as per State regulation.

**Newly Scheduled Controlled Substance Inventory**

1. When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.

|  |  |
| --- | --- |
| Title | Date |
| SIGNATURE: |  |

Attachment:

**Controlled Substance Inventory Cover Sheet**

Name of Pharmacy:

Address of Pharmacy:

DEA Number of Registrant:

Inventory Date:

Inventory Time:

Before Opening:

After Opening:

Names of Persons Conducting Inventory:

Signature of Persons Conducting Inventory:

Attachment:

**Inventory Forms or Logs:**

Example

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Drug Name | Strength | Dosage Form | Commercial Finished Form | Total Commercial Containers | Quantity On hand | Schedule |
| Oxycodone | 5 MG | Capsule | 100 | 4 | 428 | 2 |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Signature of Person Responsible for taking inventory: | | | |  |  |  |