**Purpose:**

To implement a streamlined process for ordering, monitoring, and tracking Controlled Substance use in an office setting.

# Procedure:

## Ordering of Controlled Substances:

* + - To ensure accurate inventory tracking, only single-dose vials or ampules are permitted, unless a multi-dose option is the only available format.
    - Follow approved distributor instructions for proper processing of DEA 222 form.

## Receiving Controlled Substances:

* For Schedule I & II:
  + An invoice must be matched with the Drug Enforcement Administration (DEA) 222 form to verify accuracy in quantity, strength, and medication type.
  + The date of receipt and quantity received should be documented directly on the DEA 222 form.
  + The completed DEA 222 form must be retained at the site for a minimum of two years, in accordance with regulatory requirements.
* Schedule III, IV, & V:
  + The DEA 222 form is not required but does require that all purchase records, such as invoices and packing slips, to be maintained for a minimum of two years.

## Storage and Maintenance of Controlled Substances:

* + - Controlled Substances must be stored in a centralized location at each site. If additional storage areas are warranted due to office size, then the same regulatory standards must be applied to each location.
    - Controlled Substances must be secured in a double-locked cabinet or storage area.
    - Non-Controlled and Controlled Substances may be stored and maintained similarly, at the site’s discretion.
    - Recommendation is to utilize Summit’s internal Controlled Substance Database to monitor medication stock, usage, and waste for consistency and reliability.
    - The following information must be documented in the Controlled Substance Database for each patient:
* Date of Injection
* Patient Name
* Provider Name
* Quantity Administered
* Waste
* Witness signature (if applicable)
  + - All administered Controlled Substances must also be documented in the Electronic Medical Record (EMR).
    - Documentation must include supervising physician’s signature to ensure compliance and accountability.
    - Access to Controlled Substance storage keys should be limited to the fewest appropriate individuals necessary.
    - Each month, the site must print an Inventory log of all Controlled Substances administered.
    - A copy of the invoice must be attached to the printed log which will clearly reflect the total inventory.

## Monitoring Controlled Substances:

* + - Monthly Reconciliation: Medication stock levels must be reconciled with the Controlled Substance Log monthly. Each reconciliation must include a document log entry and be witnessed by two individuals/staff.
    - Discrepancy Protocol: Any discrepancies identified must be reported to the Site Manager and Managing Partner immediately.
    - Upon discovery, the *Controlled Substance Log* must be reconciled without delay, and a copy of the updated log must be sent to Central within 24 hours to the Legal Department for further review.
    - Logbook Maintenance: Each site must maintain a Controlled Substance Logbook that includes:
* A printed copy of each month’s log
* Copies of all related invoices

**Annual Review of Controlled Substances:**

* + - The Controlled Substance Logbook will be reviewed annually as part of the Site Risk Assessment.

## Inventory Maintenance of Controlled Substances:

* Each site is required to maintain an inventory system that ensures accurate tracking of all Controlled Substances.
* Recommendation is to utilize Summit’s Internal Controlled Substance Database to monitor medication stock, usage, and waste for consistency and reliability.
* The inventory system must accurately document the disposition of all Controlled Substances, including:
  + Medications received
  + Medications Dispensed
  + Medications returned to a reverse distributor
  + Medication waste
* To support ongoing accuracy, it is recommended that the inventory be reconciled with the Controlled Substance Log on a weekly basis.

## Disposal of Controlled Substances:

* If a multi-dose vial has been opened or accessed (e.g. needle-punctured), it must be dated and discarded within 28 days unless the manufacturer specifies a different expiration period for the opened vial.
* Unused medication may be disposed of in the site’s Sharps container, following standard safety protocols.
* All disposals must be witnessed and documented by two staff members in the Controlled Substance Database and on DEA 41 form, ensuring accountability and compliance.
* The completed DEA 41 form must be retained at the site for a minimum of two years, in accordance with regulatory requirements.

**Controlled Substance Medications brought into the Office for Administration only:**

* All administered Controlled Substances must also be documented in the Electronic Medical Record (EMR).
* Documentation must include supervising physician’s signature to ensure compliance and accountability.
* Record the medication details:
  + Medication name and dosage
  + Lot and NDC number
  + Prescribing provider
  + Date of administration
  + Patient name
  + Route of injection
  + Name of staff completing administration of medication
* Document any waste or unused portion on the DEA form 41.
* The completed DEA form must be retained at the site for a minimum of two years, in accordance with regulatory requirements.