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.