5.6 Controlled Substance Policy (Schedule II, III, IV, V)

Policy:

To implement a streamlined process for ordering, monitoring, and tracking controlled substance use in the office setting.

Procedure:

Ordering:

- In an effort to maintain accurate counts, only single dose vials/ampules will be permitted except where there is only a multi-dose option available.
- Follow approved distributor instructions for appropriate processing of DEA 222 form.

Receiving:

- The order is matched with the Drug Enforcement Administration (DEA) form for accuracy of quantity, strength, and medication type.
- Date of receipt and number received documented on the DEA form.
- The DEA form is filed at the site for a period of two years.

Storage and Maintenance:

- All controlled substances will be stored in one central location at the site. If additional storage areas are warranted due to size of the office, then the same regulations apply to each storage area.
- Storage/maintenance of non-controlled and controlled substances may be handled in the same manner at the site's discretion.
- One Summit approved *Controlled Substances Log* will be maintained per drug, per storage area.
- A copy of the invoice will be attached to the log which will clearly indicate the total inventory.
- All fields (Date, Patient Name, Provider Name, Amt. Given, Amt. Wasted, Admin, Witness,) of the log must be completed and witnessed upon each drug administration.
- All controlled substances administered in the office shall be documented in a note. The note must be signed by the supervising physician and stored in the visible medical record (ChartViewer in Allscripts). A new log should be maintained upon delivery of a new medication.
- Access to keys for controlled substances storage will be limited to as few appropriate individuals as possible.

Monitoring:

- Medication stock levels will be reconciled to the amounts on the *Controlled Substance Log* on a monthly basis with a documented log entry witnessed by two persons.
- Any discrepancies noted at any time must be reported to the site manager and the managing partner immediately. Upon such discrepancy, the *Controlled Substance Log* will be reconciled immediately with a copy forwarded to Central within 24 hours. Significant discrepancies reported to the Central Office will be communicated to the Legal Department
- The site will maintain a Controlled Substance Log book containing a printed copy of each month's log with copy of invoices
- The Controlled Substance Log book will be reviewed during the yearly Site Risk Assessment.

Inventory Maintenance:

- An inventory system that assures accuracy of all controlled substances is required. The inventory system may be manual or computerized as long as the disposition of all controlled substances (e.g. all controlled substances received, dispensed, or returned to reverse distributorship) is accurately tracked. It is highly recommended the inventory versus log is reconciled weekly.

Disposal:

- If a multi-dose vial has been opened or accessed (e.g. needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- Sites may use their Sharp's box for disposal of the unused medication.
- Disposal is to be witnessed and documented by two staff members.