Federal Requirements
For Dispensing Physicians

This document serves as an informational reminder of the recordkeeping and security requirements for physicians that dispense/administer controlled substances. The proper handling of controlled drugs is a major responsibility that should not be taken lightly.

Each DEA registrant type (manufacturer, distributor, pharmacy, physician, etc.) is required to comply with specific recordkeeping requirements. These records provide DEA Investigators with the ability to conduct audits of certain controlled substances. The Code of Federal Regulation (CFR) citations are provided – and can be read in their entirety on our website (www.deadiversion.usdoj.gov)

Registration Requirements

Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance – shall obtain a DEA Registration. CFR 1301.11(a)

A separate registration is required to each principal place of business where controlled substances are distributed and/or dispensed by a person. CFR 1301.12(a)

Dispensing Physician

Recordkeeping

All required records must be maintained for at least 2 years – for inspection and copying by DEA. CFR 1304.04(a)

Inventory Requirements

Inventories are records of all controlled substances on hand on a certain date. Inventories must be kept at registered location, indicate close or beginning of business (COB/BOB), and contain: CFR 1304.11(a)

- The name of the substance
- The finished form of the substance (10mg tab)
- The # of units in each container (100 tab bottle)
- The # of containers (Four 100-tab bottles)

Initial Inventory – Taken when you first engage in dispensing. CFR 1304.11(b)

Biennial Inventory – Taken at least once every two years. CFR 1304.11(c)

Acquisition Records

Must keep a complete and accurate record of controlled substances received. CFR 1304.21(a)

Must record the date of receipt on the invoice. CFR 1304.21(d)

CII acquisition records must be on DEA Forms-222. CFR 1305.03
CIII-V acquisition records (invoices) must contain: CFR 1304.22(b)

- Name, address, and DEA # of purchaser
- Date, name of drug, strength, and quantity

A prescription may not be issued to obtain office stock. CFR 1306.04(b)

Dispensing Records

General dispensing records must be maintained in a log (kept at registered location) which contains: CFR 1304.22(c)

- The Name of the Substance
- Each Finished Form (10mg tab) & The Number of Units
- Name & Address of the Person to whom it was Dispensed
- Date of Dispensing
- Number of Units Dispensed
- Written or Typewritten Name or Initials of the Dispenser

Theft or Loss – DEA must be notified (in writing) within one business day of discovery. A DEA Form-106 must be completed. CFR 1301.76(b)

Returns & Drug Disposal – Must maintain records of drugs which are returned to Distributors – or sent for destruction through DEA licensed Reverse Distributors. These are distribution records (CII = DEA Form-222 / CIII-V = Invoices)

DEA Registrants are only allowed to acquire controlled substances from other DEA registered entities. ** **Do not accept medication from patients** **

Security

CII-V drugs must be kept in a securely locked, substantially constructed cabinet. CFR 1301.75(b)

All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. CFR 1301.71(a)