Managing the Regulatory Environment
ADA’s Guidelines for Practice Success™ (GPS™)

ADA Tip Sheet on the Safety and Inventory of Controlled Substances

The Drug Enforcement Administration’s (DEA) Controlled Substances Security Manual contains a number of General Security Requirements to assist practices that maintain inventories of any controlled substances on-site. Its Security Manual’s Security Requirements for Practitioners can help you determine whether your practice’s controlled substance security measures are sufficient and ensure that inventory records are accurate and up-to-date at all times. In addition to being a general best practice, following the rules to safeguard controlled substances can save you money – DEA Duty Investigators can assess fines of up to $10,000 for each recordkeeping deficiency.

Some general considerations regarding keeping controlled substances in the practice include:

- Safely storing them in a substantially constructed cabinet or another secure storage place, such as a safe or vault

- Limiting access to only a limited number of employees
  - Employees with access should not have any felony or misdemeanor convictions, any pending charges relating to criminal offenses, and not knowingly used narcotics other than those prescribed by a physician.
  - Consider conducting background checks on all employees with access to controlled substances.
  - Do not allow access by any employee whose DEA registration has been revoked or denied.

- Monitoring inventory and distribution through accurate and up-to-date centralized records and drug logs
  - Track and maintain all purchasing receipts to aid in monitoring inventory flow
  - Record what drugs came in when, where they went and to whom they were given or prescribed
  - Conduct a biennial inventory review in which two staff members perform separate counts of the inventory.
    - Having two people conduct separate inventories is a best practice that offers the benefit of a check and balance to be sure the proper controls are in place
  - Maintain all receiving, dispensing and disposal records with your inventory
    - Notify the DEA immediately of any theft or significant loss of any controlled substance.
      - Do that by submitting a completed Theft or Loss of Controlled Substances - DEA Form 106
    - Always confirm that the physical contents of any shipments of Schedule II narcotics match the details on the forms sent by the shipper
      - Note any discrepancies on the forms and in your inventory log
      - Inform the shipper of any discrepancies

- Developing a detailed, ongoing inventory of all Schedule II substances
  - The inventory can be typed, written or printed and must:
    - specify the date the inventory was conducted
    - detail whether it was taken at the beginning or at the close of the day
    - include the signature of the person who conducted or confirmed the inventory
    - be kept for at least two years
      - Contact your local dental association or licensing agency to find out if your state requires a longer record retention period.
The DEA has specific inventory requirements for healthcare settings that dispense Schedule II substances. If your practice dispenses controlled substances, your inventory should also include:

- the name of each substance, its finished form (such as “tablet”), and the number of milligrams
- the number of dosage units of each finished form in the commercial container (such as the number of tablets per bottle)
- the number of commercial containers for each finished form (i.e. the number of bottles for each type of tablet)
- how the substances were dispensed and/or disposed
- It’s also recommended that you maintain a daily log to track substances that are dispensed or administered to patients. Be sure to include:
  - the date a drug was dispensed or administered
  - the name of the drug used
  - the amount given
  - the name of the patient receiving the medication
  - the initials of the individual who administered or dispensed the medication

Keep in mind that multi-location practices that transport drugs between offices should track interoffice movement of Schedule II drugs using the Drug Enforcement Administration’s (DEA) Form 222. Drugs in Schedules III-V, which have less potential for addiction, can be transported without using Form 222 but similar documentation must be maintained.

Additional information is available in the DEA Practitioner’s Manual: An Informational Outline of the Controlled Substances Act and in the ADA FAQ on New Hydrocodone Combination Products (HCP) Regulations and the ADA FAQ on New Hydrocodone Combination Products (HCP) Regulations, Part 2.

Resources:

- DEA General Security Requirements
- DEA Security Requirements for Practitioners
- DEA Theft or Loss of Controlled Substances - DEA Form 106
- DEA inventory requirements For Dispensing Practices
- DEA Form 222
- DEA Practitioner’s Manual: An Informational Outline of the Controlled Substances Act
- ADA FAQ on New HCP Regulations
- ADA FAQ on New HCP Regulations, Part 2