

# 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  - Do not allow access by any employee whose DEA registration has been revoked or denied.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](#)

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