RxLegal

Federal Controlled Substances Act: Ordering and Recordkeeping

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This third of a 4-part series on key components of the Federal Controlled Substances Act will discuss ordering and recordkeeping requirements. Schedule I and II controlled substances may be ordered by filling out a Drug Enforcement Agency (DEA) Form 222 or by electronically completing the DEA Controlled Substance Ordering System (CSOS).¹ A sample Form 222 may be found on the DEA Diversion Web site at: http://www.deaiversion.usdoj.gov/pubs/manuals/pract/appendices/app_h/222.htm.² This official form is required for every distribution, purchase, or transfer of a Schedule II controlled substance.¹ In some instances, a medication may be switched from Schedule II to another Schedule at the federal level, but remain a Schedule II controlled substance at the state level. When this occurs, the stricter state law applies; many states may still require the use of Form 222 for any transaction involving a substance classified as Schedule II under the state law.

Official DEA order forms for Schedule II controlled substances must be maintained separately from other business records in the pharmacy.¹ These documents are available in books that contain 7 sets of forms. Generally, an individual pharmacy is given no more than 6 books at a time; however, more books may be allowed in specific situations. When ordering Schedule II medications, the number of packages, size of the package, and name of the item must be filled out completely on the form. Each form must be signed and dated by an authorized individual. For any individual pharmacy, there may be more than one person who is authorized to obtain and execute official DEA order forms for Schedule II medications. The pharmacy must grant a "power of attorney" to each authorized person. This power of attorney must be signed by the individual receiving authorization responsibilities and by the person who signed the most recent application for registration or renewal registration for the pharmacy.

Any sign of alteration on a DEA order form may be enough for a drug supplier to refuse a Schedule II controlled substances order.¹ A supplier may substitute identical drug products that differ in package size from those on the original order form. The only caveats to this substitution policy is that the actual quantity of Schedule II medication may not exceed the amount initially ordered and the National Drug Code (NDC) number must reflect that of the actual medication that was shipped to the purchaser.

Electronic ordering through the DEA CSOS is another option for obtaining controlled substances.¹ The CSOS allows for secure electronic transmission of controlled substance orders without supporting paper documentation. CSOS is currently the only acceptable way to electronically transmit Schedule II controlled substance orders. Users must obtain a digital certificate for ordering. These digital certificates may only be obtained by DEA registrants and individuals who are granted power of attorney by registrants. Each registrant must appoint a CSOS coordinator who acts as an agent regarding any issues related to digital certificates issued under the registrant's DEA number. Digital certificates are valid until DEA registration expires or until the DEA Certification Authority is notified that the certificate should be revoked for various reasons. Records of electronic Schedule II orders must be maintained in an electronic format for 2 years. More information on CSOS, including how to enroll, may be obtained at the DEA E-Commerce Program Web site (<http://www.deaecom.gov/>).

For Schedules III to V controlled substances, the pharmacy must maintain receipts in a readily retrievable manner.¹ A receipt may be an invoice or packing slip where the pharmacy records both the date the Schedule III to V controlled substances were received and confirmation that the order is accurate. These receipts must also contain controlled substance

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name, dosage form, number of dosage units of the dosage form in each container, and number of containers ordered and received.

Pharmacies must keep an accurate record of every transaction involving a controlled substance (ie, purchasing, receiving, dispensing, or disposal). This allows for tracking of each controlled substance from initial manufacture to final dispensing to the patient or disposal.¹ A pharmacy must maintain these records for at least 2 years. Records involving Schedule II medications must be maintained separately from all other records. Records for Schedules III to V medications may either be maintained separately or be stored with other ordinary business records, but there must be some mechanism that allows for them to be “readily retrievable.” **Table 1** summarizes records that must be maintained with regard to controlled substances.

Under federal law, there are 2 options for filing controlled substances prescriptions.¹ Sometimes, state and federal laws conflict with regard to prescription filing requirements. When this occurs, the pharmacy must choose a system from the 2 options that would comply with both state and federal requirements. The 2 filing options are summarized in **Table 2**; all controlled substances prescriptions must be readily retrievable by the DEA regardless of the option chosen by the pharmacy.

In addition, the Controlled Substances Act requires that an inventory of controlled substances in a pharmacy be conducted initially (ie, when a DEA registration has been issued) and biennially (ie, every 2

Table 2. Filing options for controlled substances prescriptions¹

Options	Requirements
#1	Three separate files: <ul style="list-style-type: none"> • One file for Schedule II medications • One file for Schedule III to V medications • One file for all noncontrolled medications
#2	Two separate files: <ul style="list-style-type: none"> • One file for Schedule II medications • One file for all other prescriptions (Schedule III to V and noncontrolled medications)

years) thereafter.¹ The Act requires an actual physical count of all Schedule II medications and an estimated count or measure of the contents of all Schedule III to V controlled substances. The exception to the estimated count would be for containers that hold more than 1,000 tablets or capsules. In that case, an exact count of the contents of the container must be undertaken. All inventory records must be maintained at the pharmacy in a readily retrievable manner for at least 2 years; Schedule II inventory records must be maintained separately from all other controlled substances. At the initial inventory, the record of the inventory must include:

- Date of the inventory
- Whether the inventory was performed at the start or close of the business day
- Name of each controlled substance that was inventoried
- Finished dosage form of each controlled substance
- Number of dosage units of each finished dosage form in the commercial container
- Number of commercial containers of each finished dosage form
- Count of each controlled substance as mentioned above

The biennial inventory requires documentation of the same information as the initial inventory and may be completed on any date within 2 years of the previous inventory date.¹ Copies of either the initial or subsequent biennial inventories do not need to be submitted to the DEA.

The fourth and final column in this series will discuss dispensing requirements, electronic controlled substances prescriptions, and fraudulent controlled substances prescriptions.

Table 1. Controlled substances records¹

- Official order forms for Schedule II medications (DEA Form 222)
- Power of attorney authorization forms
- Receipts and invoices related to Schedule III to V medications
- All controlled substances inventory records
- Records of controlled substances distributed (ie, returns to vendors, sales to other registrants, etc)
- Prescriptions for controlled substances
- Forms related to loss or theft of a controlled substance
- Forms related to controlled substances surrendered for disposal
- Records dealing with transfers of controlled substances between pharmacies
- DEA registration certificate
- Self-certification certificate and logbook as required under the Combat Methamphetamine Epidemic Act of 2005

Note: DEA = Drug Enforcement Agency.

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