CONTROLLED SUBSTANCES – OFFICE PRACTICE

Physician office practice guidelines for prescribing, safeguarding, dispensing, personnel limitations, recordkeeping, storage and disposal of controlled substances are addressed in this Medical Legal Guideline. A useful resource to also review is the DEA’s Practitioner’s Manual available from their website at http://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

I. PRESCRIBING

A. Prescriptions for Schedule II – V controlled substances requirements:

1. Be dated the day it is issued.
2. Full name and address of prescriber.
3. Full name and address of patient.
4. DEA number of the prescriber (that is authorized to prescribe said drug).
5. Affix unique identifier or written signature.
6. If written, be in an indelible medium.
7. Specify drug name length, dosage and form.
8. Specify quantity both written and numeric.
9. Include direction for use.
10. Be for a valid medical reason.
11. If electronic comply with the e-prescribing guidelines from the federal government.
12. Have no more than 5 refills, except Schedule II which may not be refilled.

B. Schedule II prescriptions are also limited:

1. No refills.
2. No more than a 30 day supply.
3. Have only one prescription per prescription blank.
4. If issued to be filled at a later date, add a “do not fill until” date.
5. Schedule II prescriptions expire in 90 days.

C. Schedule III-V prescriptions expire in 6 months.

D. In the case of an emergency, a prescriber may issue a lawful oral prescription, where failure to issue might result in loss of life or intense suffering. The oral prescription shall include a statement concerning the circumstances constituting the emergency for which the oral prescription was used. Within 7 days after issuing an emergency prescription, the prescriber shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall comply with all aspects enumerated in 720 ILCS 570/309.
II. **RECOMMENDED SAFEGUARDS FOR PRESCRIBERS**

Federal rules recommend additional measures to ensure security. These include:

1. Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
2. Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
3. Use prescription blanks only for writing a prescription order and not for notes.
5. Assist the pharmacist when they telephone to verify information about a prescription order. A corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
6. Contact the nearest DEA field office to obtain or to furnish information regarding suspicious prescription activities.
7. Use tamper-resistant prescription pads.


III. **DISPENSING**

A physician licensed to practice medicine in all its branches has authority “to purchase legend drugs requiring an order of a person authorized to prescribe drugs, and to dispense such legend drugs in the regular course of practicing medicine.”

A. The dispensing of such legend drugs shall be the personal act of the person licensed under this Act and may not be delegated to any other person not licensed under this Act or the Pharmacy Practice Act unless such delegated dispensing functions are under the direct supervision of the physician authorized to dispense legend drugs.

B. Except when dispensing manufacturers’ samples or other legend drugs in a maximum 72 hour supply, persons licensed under this Act shall maintain a book or file of prescriptions as required in the Pharmacy Practice Act.

C. Any person licensed under this Act who dispenses any drug or medicine shall dispense such drug or medicine in good faith and shall affix to the box, bottle, vessel or package containing the same a label indicating (a) the date on which such drug or medicine is dispensed; (b) the name of the patient; (c) the last name of the person dispensing such
drug or medicine; (d) the directions for use thereof; and (e) the proprietary name or names or, if there are none, the established name or names of the drug or medicine, the dosage and quantity, except as otherwise authorized by regulation of the Department of Professional Regulation. The foregoing labeling requirements shall not apply to drugs or medicines in a package which bears a label of the manufacturer containing information describing its contents which is in compliance with requirements of the Federal Food, Drug, and Cosmetic Act and the Illinois Food, Drug, and Cosmetic Act. "Drug" and "medicine" have the meaning ascribed to them in the Pharmacy Practice Act, as now or hereafter amended; "good faith" has the meaning ascribed to it in subsection (v) of Section 102 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended.

D. Prior to dispensing a prescription to a patient, the physician shall offer a written prescription to the patient which the patient may elect to have filled by the physician or any licensed pharmacy.

E. Report to the Illinois Prescription Monitoring Program within 7 days go to http://ilpmp.org to see detailed information. A civil fine up to $100 a day per dispended controlled substance may be assessed for tardiness.

F. Keep appropriate records (see record keeping).

G. Dispense in an appropriate container for patient and drug.

IV. Personnel Limitations

Registrants should not employ as an agent or employee who has access to controlled substances:

1. Any person who has been convicted of a felony offense related to controlled substances.
2. Any person who has been denied a DEA registration.
3. Any person who has had a DEA registration revoked.
4. Any person who has surrendered a DEA registration for cause.

Lastly, practitioners should notify the DEA, upon discovery, of any thefts or significant losses of controlled substances and complete a DEA Form 106 regarding such theft or loss.

V. Record Keeping
Federal rules specify record-keeping and inventory requirements. According to the DEA Practitioner Manual, these are as follows:

A. Recordkeeping Requirements

Each practitioner must maintain inventories and records of controlled substances listed in Schedules I and II separately from all other records maintained by the registrant. Likewise, inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or in such a form that they are readily retrievable from the ordinary business records of the practitioner.

All records related to controlled substances must be maintained and be available for inspection for a minimum of two years.

A registered practitioner is required to keep records of controlled substances that are dispensed to the patient, other than by prescribing or administering, in the lawful course of professional practice.

A registered practitioner is not required to keep records of controlled substances that are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment.

A registered practitioner is not required to keep records of controlled substances that are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered.

A registered practitioner is also required to keep records of controlled substances administered in the course of maintenance or detoxification treatment of an individual.

B. Inventory

Each registrant who maintains an inventory of controlled substances must maintain a complete and accurate record of the controlled substances on hand and the date that the inventory was conducted. This record must be in written, typewritten, or printed form and be maintained at the registered location for at least two years from the date that the inventory was conducted. After an initial inventory is taken, the registrant shall take a new inventory of all controlled substances on hand at least every two years. Each inventory must contain the following information:
1. Whether the inventory was taken at the beginning or close of business.
2. Names of controlled substances.
3. Each finished form of the substances (e.g., 100 milligram tablet).
4. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle).
5. The number of commercial containers of each finished form (e.g., four 100 tablet bottles).
6. Disposition of the controlled substances.

It is important to note that inventory requirements extend to controlled substance samples provided to practitioners by pharmaceutical companies.
(DEA Practitioner Manual, pgs. 16-17, 2006)

Additionally, registrants should keep thorough records for at least 5 years.

VI. **Storage Requirements**

Federal law requires practitioners to store Schedule II through V controlled substances in a securely locked, substantially constructed cabinet. Practitioners authorized to possess carfentanil, etorphine hydrochloride, and/or diprenorphine must store these controlled substances in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

Federal rules also require that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances. A list of factors is used to determine the adequacy of these security controls. Factors considered include:

1. The location of the premises and the relationship such location bears on security needs.
2. The type of building and office construction.
3. The type and quantity of controlled substances stored on the premises.
4. The type of storage medium (safe, vault, or steel cabinet).
5. The control of public access to the facility.
6. The adequacy of registrant’s monitoring system (alarms and detection systems).
7. The availability of local police protection.

VII. **Disposal**

1. DEA has take-back days. Contact your local DEA office for more information.
2. A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as “Reverse Distributors.” The practitioner should contact the local DEA field office (See Appendix E) for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years. (DEA Practitioner Manual, pg.17, 2006)

3. For more see the “Disposal of Prescription Drugs” Medical Legal Guideline. (10/2011)

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