

## RECORD-KEEPING AND DISPENSING REQUIREMENTS FOR PHYSICIANS WHO DISPENSE

- I. Dispense all drugs in a USP approved tight, light resistant container with a safety closure. If the patient does not wish a safety closure, a signed release should be obtained from the patient for the protection of the physician. Drugs must be properly stored in a location that includes protection from moisture, freezing and excessive heat, or as directed by the labeling.
- II. Affix a label to the outside of the container showing:
  - (a) date of filling;
  - (b) a serial number that refers to a log, prescription, or other record of a specific order for a specific patient;
  - (c) dispenser's name and address;
  - (d) name of the patient;
  - (e) name of the prescriber;
  - (f) directions for use;
  - (g) name of the drug; and
  - (h) any cautionary statements required by law.

If the drug is a controlled substance listed in schedule II, III, or IV, a label must also be attached stating: "**Caution: Federal law prohibits the transfer of this drug to anyone other than to whom prescribed.**"

All records relating to controlled substances must be readily retrievable and uniformly maintained. This record must be separate from the patients' charts.

- III. The physician must dispense the drugs. Although office personnel, including physician assistants and nurse practitioners, may provide technical assistance in the preparation or packaging of the drugs, they are not licensed or authorized to dispense medication. Thus the physician must be on the premises whenever drugs are dispensed.
- IV. Repackaging of drugs (i.e., taking drugs from a large container and placing into smaller containers before dispensing) in advance of need may require separate licensing.
- V. Inventory all controlled substances when drugs are first acquired. Every two years following the date of the initial inventory take a new inventory. The inventory record must:
  - (a) list the name, address and DEA registration number of the registrant;
  - (b) indicate the date and time the inventory is taken (i.e. opening or closing of business);
  - (c) be signed by the person or persons taking the inventory;
  - (d) be kept at the address appearing on the registration certificate for at least two years.
  - (e) list the kind and quantity of each controlled substance on hand; and
  - (f) be written in ink or typed.
- VI. Keep all records of Schedule II controlled substances separate from all other drug records.
- VII. Use DEA form 222 to order Schedule II drugs. Upon receipt of the drugs, copy three must be completed on the right-hand side showing:
  - (a) number of packages received; and
  - (b) date received.

- VIII. File records of controlled substances purchases (invoices) separately or mark and file so that they are readily retrievable from other business records. Keep purchase records of Schedule II drugs separate from those of Schedule III, IV, or V drugs. All records of purchases must show:
- (a) date of receipt
  - (b) name, address and DEA number of the person from whom received; and
  - (c) the kind and quantity of drugs received.
- IX. Keep a separate record in a bound logbook of all controlled substances administered or dispensed. Records only in patients' charts are not sufficient. This log must show:
- (a) kind and quantity of controlled substance dispensed or administered;
  - (b) date of dispensing or administering;
  - (c) name and address of the person to whom or for whose use the drug was dispensed or administered; and
  - (d) written or typewritten name or initials of the individual who dispensed or administered the substance.
- Keep records of Schedule II controlled substances separately.
- Keep all records for at least five years.
- X. Store controlled substances in a securely locked, substantially constructed cabinet or safe.
- XI. Controlled substances that are dispensed to patients (i.e. doses to take home, not drugs administered in the office or prescriptions written) must be reported to the Cabinet for Health Services twice each month. Contact Drug Control for information about the reporting procedure. (502) 564-7985 or fax (502) 564-2203
- XIII. Report any loss of controlled substances to the DEA and Kentucky Cabinet for Health Services (telephone 502/ 564-7985 for proper forms to report a loss). Also, notify the local or state police authority.
- XIV. Recommendations:
- (a) Order small quantities of controlled substances, placing orders more often to reduce theft.
  - (b) Screen patients closely who are asking for specific drugs. If you have doubts about these patients, contact area pharmacists. Often they are familiar with known drug abusers.
  - (c) Verify that your malpractice insurance covers dispensing of drugs. Some policies consider dispensing as the practice of pharmacy and therefore, a separate activity from the practice of medicine.
  - (d) OBRA '90 requires that pharmacists counsel patients about their prescriptions at the time of dispensing. Physicians already had the responsibility of medication use review and counseling with their patients. To avoid medical negligence, counseling procedures should be reviewed since no checks and balances will be provided by a pharmacist.
  - (e) Check the expiration dates on all stock every six (6) months.