Chapter Phar 6

CONTROLLED SUBSTANCES

Phar 6.01 Scope. Procedures governing the manufacture, distribution and dispensing of controlled substances pursuant to ch. 161, Stats., are set forth generally by that chapter and specifically by sections of this part of the Administrative Code.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72.

Phar 6.02 Records for dispensers of controlled substances. (1) Any pharmacy, practitioner or other DEA registrant authorized to dispense controlled substances shall maintain complete and accurate records of each such substance received, dispensed or disposed of in any other manner.

(2) Records required for dispensers by the federal controlled substances act and ch. 161, Stats., shall be maintained by the dispenser at the location where the drug is received and dispensed, and be available for inspection by authorized persons for at least 2 years from the date of such record, except prescription files which shall be kept for a period of 5 years. Financial and shipping records such as invoices and packing slips, but not executed order forms, may be kept at a central location.

(3) Required records shall be maintained as follows:

(a) Records of controlled substances listed in schedule II other than prescription orders shall be maintained separately from all other records of the dispenser.

(b) Records of controlled substances listed in schedules III, IV and V shall be maintained either separately or in such form that the information required is readily retrievable from ordinary records of the dispenser.

(c) Each dispenser of schedule II substances shall maintain the official DEA order form (DEA Form 222c) used in the procurement of such drugs at the location where the drug is received.

Note: DEA Form 222c may be obtained from the Regional Office, DEA, 1800 Dirksen Federal Bldg., 219 S. Dearborn, Chicago, Ill. 60604.

(d) Any person authorized to dispense controlled substances shall maintain complete and accurate records at the time of the dispensing transaction with the following information:

1. The name of the substance.

2. Dosage form, strength and quantity of the substance.

3. Number of units and date of receipt as well as name, address and registration number of the person from whom received.

4. Name and address of the person to whom dispensed, date of dispensing, quantity dispensed, and name or initials of individual who dispensed the substance.

(e) Records for dispensed schedule V substances shall be maintained as follows:

1. If a schedule V drug is dispensed pursuant to the prescription of a practitioner, the prescription shall be labeled and filed in accordance with the requirements for schedule III and IV drugs.

2. If a schedule V drug is dispensed other than pursuant to a prescription order, the dispenser shall make the record required by s. 161.23, Stats., at the time of the transaction in a bound controlled substance-V register.

(f) Any pharmacy, practitioner or other DEA registrant authorized to dispense controlled substances shall notify the Regional Office, DEA, 1800 Dirksen Federal Building, 219 S. Dearborn, Chicago, Illinois 60604, and the pharmacy examining board of the theft or significant loss of any controlled substances upon discovery of such theft or loss.

(4) Any pharmacy authorized to dispense controlled substances shall establish and maintain a prescription profile record system for all schedule II controlled substances dispensed for outpatient use. The required profile record shall be kept either as part of the pharmacy's uniformly maintained composite medication record system or as a separate profile record for schedule II controlled substances. The profile records shall be retained for 2 years and include at least the following information:

(a) Patient identification

(b) Drug allergies

(c) Date prescription is dispensed

(d) Prescription number

(e) Prescribing practitioner

(f) Drug product dispensed (dosage form and strength)

(g) Daily dosage

(h) Quantity of drug product dispensed

Computerized profile record systems and registered hospital patient records shall be deemed to comply with the requirements of this subsection if they contain the information specified in paragraphs (a) - (h).

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72; cr. (4), Register, May, 1978, No. 269, eff. 9-1-78.

Phar 6.03 Filing of prescriptions. (1) All prescriptions for controlled substances must be maintained on file, in chronological order, for a period of at least 5 years. Said prescriptions shall be readily accessible to enforcement personnel authorized by s. 161.51, Stats.

(2) Prescriptions for schedule II drugs shall be filed in chronological order and may be filed separately from all other prescriptions or may be

filed with prescriptions for schedule III, IV and V drugs provided all prescriptions in the file for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height, in the lower right hand corner of the prescription.

(3) Prescriptions for schedule III, IV and V substances may be filed with the prescriptions for non-controlled drugs provided that prescriptions for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height in the lower right hand corner of the prescription; or prescriptions for schedule III, IV and V substances may be filed separately. Under no circumstances shall prescriptions for schedule II drugs be filed together with prescriptions for non-controlled drugs.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72.

Phar 6.04 Purpose of issue of prescriptions. (1) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research, is not a prescription within the meaning and intent of ss. 450.07 (1) (f) and 161.38, Stats., and the person filling such a purported prescription knowingly, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances.

(2) A prescription issued by a practitioner to obtain controlled substances for the purpose of general dispensing to patients shall not be considered a valid prescription.

(3) A prescription may not be issued for dispensing of drugs listed in any schedule to a drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of an addict rehabilitation program.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72.

Phar 6.05 Dispensing controlled substances. (1) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the name, address and registration number of the practitioner, the name and quantity of the drug prescribed, and the directions for use. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice, and registered or exempted from registration under the federal controlled substances act.

(2) A pharmacist may dispense directly a controlled substance listed in schedule II, III or IV only pursuant to a prescription issued by an individual practitioner. The prescription shall be initialed and dated by the dispensing pharmacist as of the date dispensed.

(3) An individual practitioner may dispense directly a controlled substance listed in schedule II, III or IV provided that the prescription container is labeled and records are maintained in accordance with the requirements of this code. An individual practitioner shall not delegate to an employe or agent other than a pharmacist any of the functions involved in directly dispensing a controlled substance to a patient in the course of his professional practice.

(4) A prescription for a controlled substance listed in schedule II may be dispensed only pursuant to a written prescription signed by the prescribing individual practitioner, except in emergency situations. No prescription for a controlled substance listed in schedule II shall be filled unless presented for filling within 7 days following the date of issue.

(5) No pharmacy, individual practitioner or other DEA registered dispenser shall dispense at any one time, and no individual practitioner shall prescribe for dispensing at any one time, a controlled substance in any quantity exceeding a 34-day supply or 120 dosage units whichever is less, except that up to a 3 month supply of any schedule III or IV anticonvulsant substance, as determined by the directed dosage and frequency of dosage, may be prescribed and dispensed at one time.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72; am. (5), Register, January, 1975, No. 229, eff. 2-1-75.

Phar 6.06 Refilling controlled substances prescriptions. (1) No prescription for a schedule II substance shall be refilled.

(2) No prescription for a substance listed in schedule III or IV shall be filed or refilled more than 6 months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than 5 times. Each refilling of a prescription shall be entered on the prescription, initialed and dated by the pharmacist as of the date of dispensing and shall state the amount dispensed. If the pharmacist merely initials and dates the prescription, he shall be deemed to have dispensed a refill for the full amount of the prescription. Additional quantities of drugs listed in schedules III and IV may only be authorized by a prescribing practitioner through issuance of a new and separate prescription. Prescription refill information may be kept in a uniformly maintained, readily retrievable, medication profile record system provided the entry is made in the medication profile record at the time of dispensing each refill.

(3) A prescription for a drug listed in schedule V may be refilled only as expressly authorized by the practitioner. If no such authorization is given, the prescription may not be refilled.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72; am. (3), Register, September, 1975, No. 237, eff. 10-1-75.

Phar 6.07 Partial filling of controlled substances prescriptions. The partial filling of a prescription for a controlled substance listed in schedule II, III, IV or V is permissible.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72.

Phar 6.08 Labeling controlled substances prescriptions. (1) The pharmacist filling a written or oral prescription for a controlled substance shall affix to the immediate container a label showing the date of

dispensing; the pharmacy name and address; serial number of the prescription; name of the patient; name of the prescribing practitioner; directions for use and cautionary statements, if any, contained in such prescription or required by law.

(2) Individual practitioners who personally dispense any controlled substance to patients in the course of their professional practice other than by prescribing or administering shall affix to the immediate container a label showing the date of dispensing; the practitioner's name and address; the name of the patient; directions for use and cautionary statements as required by law.

History: Cr. Register, September, 1972, No. 201, eff. 10-1-72.