

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

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Phar 8.01 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 chapter.

History: Cr. Register, January, 1983, No. 326, eff. 2-1-83.

Phar 8.02 Records. (1) Any pharmacy, practitioner, or other federal drug enforcement administration registrant, as referenced in ch. 161, Stats., shall maintain complete and accurate records of each controlled substance received, manufactured, distributed, dispensed or disposed of in any other manner.

(2) Records required by the federal controlled substances act and ch. 161, Stats., shall be maintained at the location where the drug is received, manufactured, distributed or dispensed, and be available for inspection by authorized persons for at least 5 years from the date of such record. Financial and shipping records such as invoices and packing slips, but not executed order forms, may be kept at a central location. A complete and accurate biennial physical inventory of all schedule II, III, IV and V controlled substances pursuant to ss. 161.16, 161.18, 161.20 and 161.22, Stats., and ch. CSB 2, Wis. Adm. Code, on hand shall be made in conformance with all applicable federal and state laws.

(3) Required records shall be maintained as follows:

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

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

(c) The official drug enforcement administration order forms, DEA form 222, used in the procurement and distribution of schedule II substances shall be maintained at the locations from which the drug was distributed and where it is received.

(d) Any person authorized to manufacture, distribute or dispense controlled substances shall maintain complete and accurate records with the following information:

1. The name of the substance.
2. The dosage form, strength and quantity of the substance.
3. The quantity and date of distribution as well as the name, address and DEA registration number of the person to whom distributed.

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4. The number of units and date of receipt as well as the name, address and DEA registration number of the person from whom received.

5. The name and address of the person for whom dispensed, date of dispensing, quantity dispensed and name or initials of the 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 order of a practitioner, the prescription shall be labeled properly and the order filed in accordance with the requirements for schedule III and IV orders.

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., in a bound controlled substance V register at the time of the transaction.

(f) Any pharmacy, practitioner or other drug enforcement administration registrant authorized to possess controlled substances shall notify the regional office of the drug enforcement administration, the local police, and the pharmacy examining board of the theft or significant loss of any controlled substances upon discovery of such theft or loss.

Note: The Drug Enforcement Administration regional office is at 1800 Dirksen Federal Building, 219 S. Dearborn, Chicago, Illinois 60604.

(4) (a) Any registrant authorized under ch. 161, Stats., to dispense controlled substances shall establish and maintain a prescription profile record system for all schedule II controlled substances dispensed directly for outpatient use. The required profile record shall be kept either as part of the dispenser'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:

1. Identification of the patient.
2. The patient's drug allergies.
3. The date the prescription is dispensed.
4. The prescription number.
5. The name of the prescribing practitioner.
6. The name of the drug product dispensed including its dosage form and strength.
7. The daily dosage.
8. The quantity of the drug product dispensed.

(b) Computerized profile record systems and institutional outpatient records shall be deemed to comply with the requirements of this subsection if they contain the information specified in subdivisions 1. to 8.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 8.03 Filing prescription orders. (1) All controlled substance prescription orders shall be maintained on file, in chronological order, Register, January, 1983, No. 326

for a period of at least 5 years. The orders shall be readily accessible to enforcement personnel authorized by s. 161.51, Stats.

(2) Schedule II prescription orders may be filed separately from all other prescription orders or they may be filed with those for schedule III, IV and V drugs provided all orders 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 order. Under no circumstances may schedule II prescription orders be filed together with those for non-controlled drugs.

(3) Schedule III, IV and V prescription orders may be filed with those for non-controlled drugs provided that orders 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 order or orders for schedule III, IV and V substances may be filed separately.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 8.04 Purpose of issue of prescription. (1) A prescription order for a controlled substance to be effective shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her 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 dispenses 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 order within the meaning and intent of ss. 450.07 (1) (f) and 161.38, Stats. The person knowingly dispensing pursuant to such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

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

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 8.05 Dispensing. (1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain 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. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. An order 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 or she is licensed to practice and registered or exempt from registration under the federal controlled substance act.

(2) A pharmacist may dispense directly a controlled substance listed in schedule II, III or IV only pursuant to a prescription order issued by an individual practitioner. The order shall be initialed and dated by the dispensing pharmacist as of the date the prescription is dispensed. If the person accepting the medication pursuant to any prescription order for a schedule II controlled substance, as defined in s. 161.16, Stats., is not personally known to the pharmacist, there shall be written in ink, on the reverse side, the printed name, signature and address of the person.

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(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 may 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 or her professional practice.

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

(5) No pharmacy, individual practitioner or other DEA registered dispenser may dispense at any one time, and no individual practitioner may 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 90 day 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, January, 1983, No. 325, eff. 2-1-83.

Phar 8.06 Renewing prescriptions. (1) No prescription containing a schedule II substance may be renewed.

(2) No prescription containing a substance listed in schedule III or IV may be dispensed originally or renewed more than 6 months after the date on which the prescription order was issued and no such prescription authorized to be renewed may be renewed more than 5 times. Each renewal of a prescription shall be recorded on the prescription order or readily retrievable medication profile, including the date, quantity dispensed and identity of the pharmacist. Additional quantities of drugs listed in schedules III and IV may be authorized only by a prescribing practitioner through issuance of a new and separate prescription order.

(3) A prescription containing a drug listed in schedule V may be renewed only as expressly authorized by the practitioner.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 8.07 Partial dispensing. The partial dispensing of a prescription containing a controlled substance listed in schedule III, IV or V is permissible.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 8.08 Labeling prescriptions. (1) The pharmacist dispensing a prescription containing 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, contained in the prescription order or required by law.

(2) 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

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name of the patient; the directions for use; and cautionary statements contained in the prescription order or required by law.

History: Cr. Register, January, 1983, No. 326, eff. 2-1-83.

Phar 8.09 Emergency dispensing. (1) For the purpose of authorizing an oral prescription order for a schedule II controlled substance, the term "emergency" means those situations in which the prescribing practitioner determines that:

(a) Immediate administration of the controlled substance is necessary for proper treatment of the patient.

(b) No appropriate alternative treatment is available, including the administration of a drug which is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a practitioner if:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) The prescription order is immediately reduced to writing by the pharmacist and contains all information required in s. Phar 8.05, except for the signature of the practitioner.

(3) If the practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using his or her phone number as listed in the telephone directory and other good faith efforts to insure his or her identity.

(4) Within 72 hours after authorizing an emergency oral prescription, the practitioner shall cause a written prescription order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the prescription order shall contain on its face "authorization for emergency dispensing" and the date of the oral order. The written prescription order may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the 72 hour period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the oral emergency prescription order reduced to writing under sub. (2).

(b). The pharmacist shall notify the board or department of regulation and licensing if the practitioner fails to deliver the written prescription order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written prescription order of a practitioner.

History: Cr. Register, January, 1983, No. 326, eff. 2-1-83.