Chapter Phar 7

PHARMACY PRACTICE

Phar 7.01 Minimum procedures for compounding and dispensing. (1) Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:

(a) Receive electronic or oral prescription orders of a prescriber, review all original and renewal prescription orders, whether electronic, written or oral, and determine therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber.

(b) Read and interpret a prescriber's directions for use for the purpose of accurately transferring the instructions to the prescription label.

(c) Select, compound, mix, combine, measure, count and otherwise prepare drugs needed to dispense a prescription except that an agent of the pharmacist may procure, measure or count prefabricated dosage forms if a pharmacist verifies accuracy of the agent's action.

(d) Make a final check on the accuracy and correctness of the prescription. For all original and renewed prescriptions, the prescription order record shall identify the pharmacist responsible for the prescription.

(e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a patient's residence, is not satisfied by only offering to provide consultation.

(em) Transfer the prescription to the patient or agent of the patient.

(f) Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the prescription order, medication profile record or uniformly maintained and readily retrievable document the following information:

1. Date renewed.

2. Name of practitioner authorizing renewal, if different from the original prescriber.

3. Quantity of drug dispensed.

4. Identification of the pharmacist renewing the prescription.

(2) Subsection (1) (d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. Sub. (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients.

(3) A pharmacist may supervise no more than one pharmacy intern and 2 non–pharmacists engaged in compounding and dispensing activities as described in sub. (1) (c), except a higher ratio may be authorized by the board upon request to and approval by the board of a specific plan describing the manner in which additional interns or non–pharmacists shall be supervised.

(4) A system for compounding and dispensing not in conformance with subs. (1) to (3) may be used if reviewed and approved by the board.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; am. (1) (intro.), (d) and (f) (intro.), Register, August, 1991, No. 428, eff. 9–1–91; am. (1) (e), Register, January, 1996, No. 481, eff. 2–1–96; am. (1) (a), (e), (f) (intro)., (3) and cr. (1) (em), Register, December, 1998, No. 516, eff. 1–1–99; am. (1) (a), Register, November, 1999, No. 527, eff. 12–1–99.

Phar 7.02 Prescription label; name of drug or drug product dispensed. No prescription drug may be dispensed unless the prescription label discloses the brand name and strength, or the generic name, strength, and manufacturer or distributor of the drug or drug product dispensed unless the prescribing practitioner requests omission of the above information. The prescription label shall not contain the brand or generic name of any drug or drug product other than that actually dispensed.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; Register, August, 1991, No. 428, eff. 9–1–91; am. Register, January, 1996, No. 481, eff. 2–1–96.

Phar 7.03 Prescription renewal limitations. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed (PRN) by the patient, shall not be renewed beyond one year from the date originally prescribed. No prescription order containing either specific or PRN renewal authorization is valid after the patient–physician relationship has ceased.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; Register, August, 1991, No. 428, eff. 9–1–91.

Phar 7.04 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community–based residential facilities, jails or prison facilities.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their expiration date.

(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; am. Register, August, 1991, No. 428, eff. 9–1–91; r. and recr., Register, December, 1998, No. 516, eff. 1–1–99.

Phar 7.05 Prescription records. (1) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last renewal.

(2) All systems used for maintaining a record of any prescription dispensing shall include:

(a) Patient's identification.

(b) Name, strength and dosage form of the drug product dispensed.

(c) Quantity dispensed.

(d) Date of all instances of dispensing.

(e) Practitioner's identification.

(f) Pharmacist's identification.

(g) Retrieval designation.

(3) (a) Except as provided in sub. (5), the transfer of original prescription order information for the purpose of renewal dispensing is permissible between 2 pharmacies on a one–time basis pursuant to the following requirements:

1. The transfer is communicated directly between 2 pharmacists and the pharmacist making the transfer records the following information:

a. The word "VOID" is written on the face of the invalidated prescription order.

b. The name and address of the pharmacy to which it is transferred, the name of the pharmacist receiving the prescription order, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(b) The pharmacist receiving the transferred prescription order information shall record in writing the following:

1. The word "TRANSFER" on the face of the transferred prescription order.

2. The date of issuance of the original prescription order.

3. The original number of renewals authorized on the original prescription order.

4. The date the prescription was dispensed originally.

5. The number of valid renewals remaining and the date of the last renewal.

6. The pharmacy's name, address, the original prescription order number from which the prescription order information was transferred.

7. The name of the pharmacist making the transfer.

(c) The original and transferred prescription order shall be maintained for a period of 5 years from the date of the last renewal.

(4) A written copy of any prescription order for a prescribed drug provided by a pharmacist shall be identified in writing as "COPY — FOR INFORMATION ONLY". No prescribed drug may be dispensed based on an information copy.

(5) Pharmacies having access to a common central processing unit are not limited in the transfer of original prescription order information for the purpose of renewal dispensing if prior written approval is received from the board.

Note: This procedure requires a variance from the federal drug enforcement administration (DEA) for controlled substances. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537.

(6) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of original prescription order information for the purposes of renewal dispensing, if the system:

(a) Is capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining. The system shall be designed so that the pharmacy can receive the printout within 48 hours after requesting the printout.

(b) Is equipped with an auxiliary procedure which, during periods of down–time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription renewals are authorized by the original prescription order, that the maximum number of prescription renewals has not been exceeded and that all of the appropriate data are retained for on–line entry as soon as the computer system is again available for use.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; cr. (5), Register, September, 1987, No. 381, eff. 10–1–87.

Phar 7.065 Answering machines in pharmacies. Oral prescription orders may be received at a pharmacy via a telephone answering device and dispensed by the pharmacist if the voice of the physician or physician's agent is known to the pharmacist, and provided other requirements of reducing the prescription order to writing, labeling and filing are met.

History: Cr. Register, December, 1998, No. 516, eff. 1–1–99.

Phar 7.07 Medication profile record system. (1) An individual medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions, original or renewal, are dispensed for outpatient use. The system shall be capable of permitting the retrieval of information. The system need not be limited to individual medication profile records.

(2) The following minimum information shall be retrievable:

(a) Patient name, or other identifying information.

(b) Address of the patient.

(c) Birth date of the patient if obtainable.

(d) Name of the drug product dispensed.

(e) Strength of the drug product dispensed.

(f) Dosage form of the drug product dispensed.

(g) Quantity of the drug product dispensed.

(h) Directions for use.

(i) Retrieval designation assigned to the prescription order.

(j) Date of all instances of dispensing, for original and renewal prescriptions.

(k) Practitioner identification.

Note: This subsection incorporates renewal dispensing information required by federal law (21 CFR 1306.22) and state law (s. 450.11 (5), Stats.).

(3) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(4) At the time a prescription order is reviewed by the pharmacist for dispensing, the pharmacist shall review the medication profile record of the patient for the previously dispensed medication history and shall determine whether the prescription order presented should be dispensed.

(5) Medication profile records, if used as the only documentation of renewal dispensing, shall be maintained for a period of not

less than 5 years following the date of the last entry. If the profile records are not used as the only documentation of renewal dispensing they shall be maintained for a period of not less than 1 year from the date of the last entry.

History: Cr. Register, January, 1989, No. 397, eff. 2–1–89; renum. from Phar 7.08, Register, August, 1991, No. 428, eff. 9–1–91; am. (1), Register, December, 1998, No. 516, eff. 1–1–99.

Phar 7.08 Prescription orders transmitted electronically. (1) Except as provided in s. 453.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

Note: Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders, subject to the same requirements for oral emergency orders for schedule II controlled substances. See s. 961.38 (1r) and (2), Stats., and s. Phar 8.09.

(2) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order does all of the following:

(a) Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

(b) Identifies the individual sender's name and telephone number for oral confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission.

(c) Is designated "electronically transmitted prescription", or with similar words or abbreviations to that effect.

(d) Contains all other information that is required in a prescription order.

(3) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.

(4) Any visual or electronic document received in connection with an electronically transmitted prescription order shall be accessible only within the professional service area of the pharmacy to protect patient confidentiality and assure security.

(5) A pharmacist who receives a prescription order electronically shall ensure the security, integrity and confidentiality of the prescription order and any information contained in the order. To maintain the confidentiality of patient records, the electronic system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the prescription has been dispensed, any alterations in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration.

(6) Access to the electronic mail system for the receipt of prescription orders electronically may only be acquired by use of a password or passwords, known only to individuals authorized to access the system.

(7) A pharmacist may not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent other pharmacy laws.

History: Cr. Register, November, 1999, No. 527, eff. 12–1–99.

Phar 7.09 Automated dispensing systems. (1) In this section:

(a) "Automated dispensing system" means a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, or tuberculosis sanitorium, but does not include community–based residential facilities.

(2) An automated dispensing system may be used in a community pharmacy, as provided in this section.

(3) An automated dispensing system may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. An automated dispensing system used by an institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community pharmacy or an institutional pharmacy is responsible for all of the following:

(a) Assuring that the automated dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complying with the recordkeeping and security safeguards pursuant to sub. (5).

(b) Implementing an ongoing quality assurance program that monitors performance of the automated dispensing system, which is evidenced by written policies and procedures.

(c) Providing the board with prior written notice of the installation or removal of an automated dispensing system. The notice provided shall include, but is not limited to the:

1. Name and address of the pharmacy.

2. Initial location of the automated dispensing system. The automated dispensing system may thereafter be relocated within the pharmacy or inpatient health care facility without providing subsequent notification to the board.

3. Identification of the managing pharmacist.

(d) Assigning, discontinuing or changing personnel access to the system.

(e) Assuring that access to the medications comply with state and federal laws.

(f) Assuring that the automated dispensing system is stocked accurately and in accordance with established written policies and procedures.

(5) An automated dispensing system shall comply with the following provisions:

(a) A pharmacy shall maintain on–site the following documentation relating to an automated dispensing system:

1. Name and address of the pharmacy or inpatient health care facility where the system is being used.

2. The system manufacturer's name, model and serial number.

3. Description of how the system is used.

4. Written quality assurance procedures to determine continued appropriate use of the system.

5. Except as required pursuant to par. (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(b) All written policies and procedures shall be maintained in the pharmacy responsible for the automated dispensing system.

(c) An automated dispensing system shall have adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(d) Records and data kept by the automated dispensing system shall meet the following requirements:

1. All events involving the contents of the automated dispensing systems must be recorded electronically.

2. Records shall be maintained by the pharmacy and be available to the board. Records shall include:

a. The time and location of the system accessed.

b. Identification of the individual accessing the system.

c. Type of transaction.

d. Name, strength, dosage form and quantity of the drug accessed.

e. Name of the patient for whom the drug was ordered.

f. Such additional information as the managing pharmacist may deem necessary.

(e) The stocking of all medications in the automated dispensing system shall be accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an automated dispensing system is located within a pharmacy the supervision must be direct.

(f) A record of medications stocked into an automated dispensing system shall be maintained for 5 years and shall include identification of the person stocking and pharmacist checking for accuracy.

(g) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with state and federal law.

(h) All aspects of handling controlled substances shall meet the requirements of all state and federal law.

(i) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, in accordance with state and federal law.

(j) The automated dispensing system shall provide a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

History: Cr. Register, October, 2000, No. 538, eff. 11–1–00.

Phar 7.10 Administration of drug products and devices other than vaccines. A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats., in the course of teaching a patient self–administration techniques except a pharmacist may not administer by injection a prescribed drug product or device unless he or she satisfies each of the following:

(1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the American council on pharmaceutical education or the board, in injection techniques, emergency procedures and record keeping.

(2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration by injection of prescribed drug products or devices in an amount that is not less than $1,000,000 for each occurrence and $2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.

(3) The pharmacist has written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self–administration techniques to a patient.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

History: Cr. Register, December, 1999, No. 528, eff. 1–1–00.