Chapter Phar 7

PHARMACY PRACTICE

Phar 7.01	Minimum procedures for compounding and dispensing.	Phar 7.07	Medication profile record system.
Phar 7.015	Pharmacy technicians.	Phar 7.08	Prescription orders transmitted electronically.
Phar 7.02	Prescription label; name of drug or drug product dispensed.	Phar 7.09	Automated dispensing systems.
Phar 7.03	Prescription renewal limitations.	Phar 7.095	Operation of remote dispensing sites.
Phar 7.04	Return or exchange of health items.	Phar 7.10	Administration of drug products and devices other than vaccines.
Phar 7.05	Prescription records.	Phar 7.12	Central fill pharmacy.
Phar 7.055	Transfer of prescription order information.	Phar 7.20	Automated technology product verification.
Phar 7.065	Answering machines in pharmacies.	Phar 7.21	Delegate−check−delegate.

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 location of the patient's choice 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 location of the patient's choice, 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. Subsection (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients.

(4) A system for compounding and dispensing not in conformance with subs. (1) and (2) 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; am. (3), Register, April, 2001, No. 544, eff. 5−1−01; CR 13−018: am. (1) (e) Register October 2013 No. 694, eff. 11−1−13; **EmR1915: emerg. r. (3), eff. 10−3−19; CR 19−022: r. (3) Register February 2020 No. 770, eff. 3−1−20; correction in (4) made under s. 13.92 (4) (b) 7., Stats., Register February 2020 No. 770**.

Phar 7.015 Pharmacy technicians. (1) As used in this section, "pharmacy technician" means a non−pharmacist or non−pharmacist intern who, under the general supervision of a pharmacist who regularly coordinates, directs and inspects the activities of the pharmacy technician, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management. "Pharmacy technician" does not include ancillary persons which include, clerks, secretaries, cashiers or delivery persons, who may be present in the pharmacy.

(2) A pharmacist may delegate technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

(a) Accepting written or electronic prescription orders of the prescribing practitioner or from the prescribing practitioner's agent.

(b) Accepting original oral prescription orders from the prescribing practitioner or prescribing practitioner's agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

(c) Requesting authorization for a refill from the prescribing practitioner.

(d) Accepting oral authorization for a refill from the prescribing practitioner or prescribing practitioner's agent, provided there are no changes to the original prescription order.

(e) Accepting a request from a patient to refill a prescription.

(f) Obtaining and entering patient or prescription data into the patient information system.

(g) Preparing a prescription label.

(h) Retrieving medication from stock, counting or measuring medication, and placing the medication in its final container.

(i) Reconstituting prefabricated dosage forms.

(j) Compounding pharmaceuticals pursuant to written policies and procedures.

(k) Affixing a prescription label to its final container.

(L) Placing ancillary information on the prescription label.

(m) Prepackaging and labeling drugs for dispensing by a pharmacist.

(n) Preparing unit dose carts for final review by a pharmacist.

(o) Retrieving and transporting stock medication to and from pharmacist approved areas.

(p) Other technical functions that do not require the professional judgment of a pharmacist.

(q) Transferring the prescription to the patient or agent of the patient, provided that the pharmacist has first provided a patient consultation.

(3) A pharmacy technician may not do any of the following:

(a) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(b) Perform any of the following tasks:

1. Participate in final drug utilization reviews.

2. Make independent therapeutic alternate drug selections.

3. Participate in final drug regimen screening, including screening for therapeutic duplication, drug−to−drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.

4. Perform any act necessary to be a managing pharmacist.

5. Administer any prescribed drug products, devices or vaccines.

(c) Provide patient counseling, consultation, or patient specific judgment, such as interpreting or applying information, including advice relating to therapeutic values, potential hazards and uses.

(4) The pharmacist shall provide the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

History: Cr. Register, April, 2001, No. 544, eff. 5−1−01; CR 07−099: cr. (2) (q), r. (3) (d) Register May 2008 No. 629, eff. 6−1−08.

Phar 7.02 Prescription label; name of drug or drug product dispensed. No drug product 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 product dispensed unless the prescribing practitioner requests omission of the above information. If a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product specified in the prescription order, the prescription label may include both the generic name of the drug product equivalent and the brand name specified in the prescription order, unless the prescribing practitioner requests that the brand name be omitted from the label. If a brand name drug product is dispensed, the prescription label may contain both the brand name and the generic name of the drug product equivalent dispensed unless the prescribing practitioner requests that the generic name of the drug product equivalent be omitted from the label.

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; CR 07−097: am. Register May 2008 No. 629, eff. 6−1−08.

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.

(c) "Original container" means the container in which a health item was sold, distributed or dispensed.

(d) "Resident health care patient" means a patient residing in a community−based residential facility that controls a resident's prescribed and over−the−counter medications as specified by s. DHS 83.37.

(e) "Secured institutional health care patient" means any of the following:

1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.

2. A juvenile patient who resides in a juvenile correctional facility, as defined in s. 938.02 (10p), Stats.; a secured residential care center for children and youth, as defined in s. 938.02 (15g), Stats.; a juvenile detention facility, as defined in s. 938.02 (10r), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.

(f) "Tamper−resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, 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 beyond use 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.

(d) For a secured institutional health care patient or resident health care patient where all of the following apply:

1. The health item was never in the possession and control of the patient.

2. The health item was sold, distributed or dispensed in a tamper−resistant package and, for a drug, includes the beyond use date and manufacturer's lot number.

3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient.

4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

(e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered.

2. The pharmacist determines the contents are not adulterated.

(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.

(3m) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or redispensed other than to a secured institutional health care patient.

(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.

(5) 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 destruction at the pharmacy or other disposal by an authorized person or entity.

Note: Cancer and chronic disease drug returns and redispensing pursuant to ch. DHS 148 are allowed provided the pharmacy follows the requirements in ch. DHS 148.

Note: A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison is not addressed in this rule. Such a drug may be redispensed to a patient in a state prison provided the requirements of s. 450.09 (7m), Stats., are satisfied.

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; CR 05−029: cr. (1) (c) to (f), (2) (d) and (e), (3m) and (5), am. (2) (intro.) and (b) Register December 2005 No, 600, eff. 1−1−06; correction in (1) (d) made under s. 13.92 (4) (b) 7., Stats., Register March 2010 No. 651; CR 13−076: am. (1) (e) 2. Register August 2014 No. 704, eff. 9−1−14.

Phar 7.05 Prescription records. (1) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill 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 refills are authorized by the original prescription order, that the maximum number of prescription refills 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.

(1m) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last refill.

(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.

History: Cr. Register, January, 1983, No. 325, eff. 2−1−83; cr. (5), Register, September, 1987, No. 381, eff. 10−1−87; CR 00−165: am. (3) (a) (intro.), (b) 6., (c), (5) and (6) (intro.), r. (3) (b) 4., cr. (3) (b) 8., Register July 2001, No. 547 eff. 8−1−01; CR 05−078: rn. (1) and (6) to be (1m) and (1) and am. (1) (intro.), (b) and (1m), r. (3) to (5) Register January 2006 No. 601, eff. 2−1−06.

Phar 7.055 Transfer of prescription order information. (1) GENERAL REQUIREMENTS. A pharmacist may transfer prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:

(a) The transfer is communicated directly between 2 pharmacists either by verbal transfer or by a computer system transfer meeting the requirements of sub. (4). Communication by facsimile machine is not allowed unless the prescription order information being transferred is verified verbally between 2 pharmacists.

(b) A computer system used to record a verbal transfer of prescription order information for a non−controlled substance meets the requirements of s. Phar 7.05 (1) (a) and (b).

(c) The pharmacist receiving the verbal transfer of prescription order information for either a controlled or a non−controlled substance records the transferred information in writing unless a computer system transfer meeting the requirements of sub. (4) is used.

(d) All original and transferred prescription orders are maintained for a period of 5 years from the date of the last refill.

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

(f) A pharmacist making or receiving a transfer of prescription order information is licensed in the state in which he or she performs an act required by this section.

(2) NON−CONTROLLED SUBSTANCES. The transfer of prescription order information for non−controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

(a) The pharmacist making the transfer records the following information:

1. The word "VOID" is written on the face of the invalidated prescription order or recorded in a similar manner to "VOID" on a prescription order in a computer system meeting the requirements of s. Phar 7.05 (1) (a) and (b).

2. The name and address of the pharmacy to which it was 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 or in a computer system meeting the requirements of s. Phar 7.05 (1) (a) and (b).

3. A transfer of prescription order information for a non−controlled substance for the purposes of refill dispensing is limited to the number of authorized refills.

(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 name and address of the patient, the name and address of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.

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

4. The original number of refills authorized on the original prescription order.

5. The date of original dispensing if the prescription order has previously been dispensed.

6. The number of valid refills remaining and the date of the last refill.

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

8. The name of the pharmacist making the transfer.

9. The name, address and telephone number of the pharmacy from which the original prescription order was transferred if different than subd. 7.

(3) CONTROLLED SUBSTANCES. The transfer of prescription order information for controlled substances for the purposes of refill dispensing is permissible pursuant to the following requirements:

(a) The transfer of prescription order information is permissible only on a one time basis unless a computer system meeting the requirements of sub. (4) is used.

(b) If a computer system meeting the requirements of sub. (4) is used, a transfer of prescription order information for the purposes of refill dispensing is limited to the number of authorized refills.

(c) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist making the transfer shall record in writing the following information:

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

2. The name, address and DEA registration number of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order and the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(d) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist receiving the transferred prescription order information shall record in writing the following information:

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

2. The name and address of the patient, the name, address and DEA number of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.

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

4. The original number of refills authorized on the original prescription order.

5. The date of original dispensing.

6. The number of valid refills remaining and the dates and locations of previous refills, if applicable.

7. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order information was transferred if different from the pharmacy from which the prescription order was originally dispensed.

8. The name of the pharmacist making the transfer.

9. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order was originally dispensed.

(4) USE OF COMPUTER SYSTEM. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.05 (1) (a) and (b), contain a common central processing unit electronically sharing a real−time, on−line database to which both the transferring and receiving pharmacy have access.

History: CR 05−078: cr. Register January 2006 No. 601, eff. 2−1−06.

Note: See the table of Appellate Court Citations for Wisconsin appellate cases citing s. Phar 7.055.

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. 89.068 (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.

(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 sys-

tem 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; correction in (1) made under s. 13.92 (4) (b) 7., Stats., Register February 2017 No. 734.

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 7.095 Operation of remote dispensing sites. (1) DEFINITIONS. In this section:

(a) "Health care facility" means a facility, as defined in s. 647.01 (4), Stats., or any hospital, nursing home, community−based residential facility, county home, county infirmary, county hospital, county mental health center or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.02, 50.03, 50.35, 51.08 or 51.09, Stats., or a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42 or 252.10, Stats.

(b) "Managing pharmacist" means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(c) "Practitioner" means a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs.

(d) "Remote dispensing site" means a dispensing site that is not licensed as a pharmacy. Remote does not mean geographical distance or location.

(e) "Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of all aspects of the remote dispensing site.

(2) LICENSING REQUIREMENTS AND USE OF TITLES RELATING TO THE OPERATION OF REMOTE DISPENSING SITES. (a) A remote dispensing site shall not be licensed as a pharmacy.

(b) No person may use or display the title "pharmacy," "drugstore," "apothecary," or any other title, symbol or insignia having the same or similar meanings in connection with a remote dispensing site.

(3) LOCATION OF REMOTE DISPENSING SITES. A pharmacist may dispense at the following locations:

(a) A health care facility or a facility identified under s. 980.065, Stats.

(b) The office or clinic of a practitioner.

(c) A county jail, rehabilitation facility under s. 59.53 (8), Stats., state prison under s. 302.01, Stats., or county house of correction under s. 303.16 (1), Stats.

(d) A juvenile correctional facility under s. 938.02 (10p), Stats., juvenile detention facility under s. 938.02 (10r), Stats., residential care center for children and youth under s. 938.02 (15d), Stats., secured residential care center for children and youth under s. 938.02 (15g), Stats., type 1 juvenile correctional facility under s. 938.02 (19), Stats., type 2 residential care center for children and youth under s. 938.02 (19r), Stats., or type 2 juvenile correctional facility under s. 938.02 (20), Stats.

(4) REQUIREMENTS FOR THE OPERATION OF REMOTE DISPENSING SITES. (a) A remote dispensing site shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.

2. This store is a remote dispensing site being supervised by a pharmacist located at all of the following:

a. Name of store.

b. Address of store.

c. Telephone number of store.

3. The pharmacist is required to talk to you each time you pick up a prescription.

(b) A remote dispensing site shall not open for operation if the supervising pharmacy is closed.

(c) A remote dispensing site shall not dispense a prescribed drug or device in the absence of the ability of a patient to communicate with the pharmacist.

(d) When closed, a remote dispensing site shall have a centrally monitored alarm. For all after hour entries, the personnel entering the site shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for 2 years.

(e) A remote dispensing site shall submit written notification to the board 30 days prior to operating the remote dispensing site.

(5) DISPENSING REQUIREMENTS. A remote dispensing site shall meet all of the following:

(a) Comply with the requirements under s. Phar 7.01 and visually inspect prescription orders, labels and dispensed product.

(b) Comply with the labeling requirements under s. Phar 7.12 (2) (g). The prescription label shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.

(c) Comply with federal law if a remote dispensing site dispenses controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACISTS. (a) The managing pharmacist of a remote dispensing site shall, in accordance with s. Phar 7.09, do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. Implement an on–going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion of inventory, and documentation of remedial training to prevent future errors.

3. Visit the remote dispensing site at least monthly to conduct controlled substance inventory, to ensure written policies and procedures are being followed, and to ensure that remote dispensing site personnel comply with all federal and state laws regulating the practice of pharmacy.

4. Retain documentation of the monthly inspection visits at the remote dispensing site for 2 years.

(b) The managing pharmacist at the supervising pharmacy is responsible for all remote dispensing sites connected to the supervising pharmacy.

(7) REQUIREMENTS FOR PHARMACY TECHNICIANS AND INTERNS. Pharmacy technicians and interns employed at a remote dispensing site shall satisfy all of the following requirements:

(a) Be 18 years of age or older.

(b) Be a high school graduate or have equivalent education.

(c) Have completed 1500 hours of work as a technician within the 3 years prior to the date of employment at the remote dispensing site or completed a training program approved by the board.

History: CR 09–099: cr. Register March 2010 No. 651, eff. 4–1–10.

Phar 7.10 Administration of drug products and devices other than vaccines. (1) In this section, "course of study" means one or more classes, workshops, seminars, or continuing education programs.

(2) 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. After the pharmacist administers a prescribed drug product or device, the pharmacist, a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

(3) A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(4) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., may not administer a prescribed drug product or device unless the person satisfies all of the following:

(a) Successfully completes a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council of Pharmacy Education or the board.

(c) After administering the prescribed drug product or device, notifies the prescribing practitioner or enters the information in a patient record system shared by the prescribing practitioner.

(5) The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.

(6) A course of study and training in administration technique shall include all of the following topics:

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

(d) The five rights of administration including right patient, right drug, right dose, right route, and right time.

(e) Patient reassessment after administration including signs and symptoms of adverse drug reactions.

(f) Best practices in documentation of the medication administration.

(7) This section does not apply to the administration of vaccines.

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; CR 14–023: am. (1) Register August 2014 No. 704, eff. 9–1–14; CR 16–079: r. and recr., Register August 2017 No. 740, eff. 9–1–17; correction in (2) made under s. 35.17, Stats., Register August 2017 No. 740.

Phar 7.12 Central fill pharmacy. (1) In this section:

(a) "Central fill pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

(2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

(a) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent.

(c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8.

(d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of s. Phar 7.01 (1) (e) and (em).

(f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug utilization review, refill authorizations, interventions and drug interactions.

(g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed drug or device was dispensed for purposes of s. 450.11 (4) (a) 1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.

(h) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

(j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

(k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

(L) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

History: CR 01–075: cr. Register November 2003 No. 575, eff. 12–1–03; CR 09–098: am. (2) (f) Register May 2010 No. 653, eff. 6–1–10.

Phar 7.20 Automated technology product verification. (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizes barcodes or another machine–readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated

technology product verification which shall be made available to the board upon request.

(5) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.

3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.

4. Documentation of the dates of all software upgrades.

5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

History: EmR1916: emerg. cr., eff. 10−3−19; CR 19−023: cr. Register February 2020 No. 770, eff. 3−1−20; correction in (2) (b) made under s. 35.17, Stats., Register February 2020 No. 770.

Phar 7.21 Delegate−check−delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

(b) "Delegate−check−delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(d) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

(b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:

a. Drug name.

b. Strength.

c. Formulation.

d. Expiration date.

e. Beyond use date.

2. Common dispensing medication errors and concepts including all of the following:

a. Wrong medication.

b. Wrong strength.

c. Wrong formulation.

d. Extra or insufficient quantity.

e. Omitted medications if utilizing unit dose or compliance packaging.

f. Expired medication.

g. Look−alike or sound−alike errors.

h. High−alert medications.

3. Eligible medications for delegate−check−delegate.

4. Organizational policies and procedures on reporting of medication errors.

5. Overview of the medication use process including all of the following:

a. Procurement.

b. Ordering.

c. Dispensing.

d. Administration.

e. Monitoring.

6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:

a. Wrong drug.

b. Wrong strength.

c. Wrong formulation.

d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.

(e) Notwithstanding, pars. (a) to (d), a delegate who completed the pilot program validation process between October 1, 2016, and September 30, 2019, meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4).

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.

2. Has a drug utilization review performed by a pharmacist prior to dispensing.

3. Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if the medication meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.

2. Has a drug utilization review performed by a pharmacist prior to dispensing.

3. Includes a description of the medication on the prescription label that allows for a non−pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate−check−delegate audit shall include all of the following:

1. Name of the product verification delegate.

2. Total number of product verifications performed.

3. Number of product verifications audited by the pharmacist.

4. Percentage of product verifications audited by pharmacist.

5. Percentage of accuracy.

6. Number of product verification errors identified.

7. Type of error under sub. (2) (c) 2.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate−check−delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate−check−delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate−check−delegate which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate−check−delegate pharmacist, indicating the name of the supervising delegate−check−delegate pharmacist, and the dates the supervision responsibilities begin and end.

3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

History: EmR1917: emerg. cr., eff. 10−3−19; CR 19−024: cr. Register February 2020 No. 770, eff. 3−1−20; corrections in (1) (d), (2) (e), (3) (b) (intro.), 3. made under s. 35.17, Stats., Register February 2020 No. 770.