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PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD

Room N206, 4822 Madison Yards Way, 2nd Floor, Madison, WI 53705
Contact: Tom Ryan (608) 266-2112
November 14, 2018

Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. ***A quorum of the Board may be present during any committee meetings.***

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Legislation and Rule Matters – Discussion and Consideration (2-23)

1) Phar 7 Relating to Practice of Pharmacy
2) Updates on Legislation and Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes Administrative Rules Coordinator	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
14 November 2018	☐ Yes ☐ No	Legislative and Administrative Rule Matters 1. Phar 7 Relating to Practice of Pharmacy 2. Updates on Legislation and Pending or Possible Rulemaking Projects

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☐ Open Session ☐ Closed Session	☐ Yes ☐ No	

10) Describe the issue and action that should be addressed:

11) Authorization

Sharon Henes *mm/dd/yy*

Signature of person making this request **Date**

Supervisor (if required) **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

7.xx Automated technology final check. (1) AUTOMATED TECHNOLOGY FINAL CHECK QUALIFICATIONS. Automated technology may perform the final check of a prescription which meets all of the following:

(a) Located within the licensed pharmacy.

(b) Utilizes barcodes or machine readable technology to complete the final check.

(c) The automated technology shall be validated by the following process:

1. The automated technology shall make a final check for accuracy and correctness of a minimum of 2500 final checks and achieve an accuracy rate of at least 99.8%

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

(d) The automated technology shall be revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy of the final check is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(2) ELIGIBLE MEDICATIONS. The automated technology may do the final check if the medications meet all of the following:

(a) Contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.

(b) Is prospectively reviewed by a pharmacist for clinical appropriateness prior to leaving the pharmacy. [refer to DUR reference]

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

(3) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology final check which shall be made available to the board upon request.

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

1. All validation records of each automated technology that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.

2. Names of the supervising pharmacist including the start and end date of supervision responsibilities.

3. Documentation of managing pharmacist and supervising pharmacist of responsibilities.

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

5. Documentation of the dates of all software upgrades.

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

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

(5) SUPERVISING PHARMACIST RESPONSIBILITIES. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the ATFC program. The supervising pharmacist is the responsible for the final check made by the automated technology. [this could be under (1) (e)]

7.xx Technician-check-technician. (1) DEFINITIONS. In this section a technician means:

(2) TECHNICIAN QUALIFICATIONS. A pharmacist may delegate the final check of a prescription to the technician who meets all of the following:

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

(b) Completed a didactic and practical training curriculum that includes the following:

1. Elements of a package label.
2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication.
3. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong dose.
    c. Wrong dosage form.
    d. Extra or insufficient quantity.
    e. Omitted medications.
    f. Expired medication.
    g. Look-alike or sound-alike errors.
    h. High-alert medications.
4. Organizational policies and procedures on reporting of medication errors
5. Overview of the organization's 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 technician prior to starting the validation process.

(c) Completion of the following validation process:

1. The technician being validated shall make a final check on the work of another technician for accuracy and correctness of a minimum of 1000 final checks over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%
2. A pharmacist shall artificially introduce at least one occurrence of each of the following:
    a. Wrong drug.
    b. Wrong dose.
    c. Wrong dosage form.
    d. Extra or insufficient quantity.
    e. Omitted medication.
    f. Expired dose.
3. The pharmacist shall ensure the artificially introduced drugs in subd. 2 are removed prior to delivery to a patient care area.

4. A pharmacist shall audit 100% of the final checks made by the technician during the validation process.

(d) An assessment of the technician's accuracy shall be completed quarterly of the previous 12 months of technician-check-technician final checks. A technician shall be revalidated if the technician fails to maintain a final check accuracy rate of 99.8% or has not performed technician-check-technician final checks within the last six months.

(3) ELIGIBLE MEDICATIONS. (a) *Institutional pharmacies.* The technician may do the final check if the medications meet all of the following:

1. Contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.
2. Is prospectively reviewed by a pharmacist for clinical appropriateness prior to leaving the pharmacy.
3. Administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The technician may do the final check if the medications meet all of the following:

1. Non-compounded, non-reconstituted, no-mailed, non-delivered medications dispensed to a patient using a method to ensure the right patient is receiving the right drug, dose, and dosage form at the time of dispensing.
2. Following the pharmacy workflow assisted by technology has not been overridden.
3. Is prospectively reviewed by a pharmacist for clinical appropriateness prior to leaving the pharmacy.
4. Is dispensed with a patient consultation which affords the pharmacist and patient a visual check of the medication before it is dispensed or includes a description on the prescription label for the patient to visually check the medication after it is dispensed.

(4) QUALITY ASSURANCE. A minimum of 5% of all technician-check-technician final checks shall be audited by a licensed pharmacist each day that a technician performs a final check. The accuracy of each technician shall be tracked individually.

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

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

1. All validation records of each technician that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
2. Names of the supervising technician-check-technician pharmacist including the start and end date of supervision responsibilities.
3. Daily quality assurance logs of the 5% pharmacist technician-check-technician audit including all of the following:
    a. Name of the technician.
    b. Total number of final checks performed.
    c. Number of final checks audited by the pharmacist.

d. Percentage of final checks audited by pharmacist.
e. Number of final check errors identified.
f. Type of error.

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

Automated Dispensing Systems

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.

NABP Model Rules

Section 9. Automated Pharmacy Systems.

(a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies located within an Institutional Facility or clinic. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and Shared Pharmacy Services Pharmacy location shall be maintained in the Pharmacy for review . Such documentation shall include, but is not limited to:
   (i) name and address of the Pharmacy and the Shared Pharmacy Services Pharmacy where the Automated Pharmacy System(s) is being used;
   (ii) Manufacturer's name and model;
   (iii) description of how the Automated Pharmacy System is used;
   (iv) quality assurance procedures to determine continued appropriate use of the Automated Pharmacy System;
   (v) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction; and
   (vi) documentation evidencing that the Automated Pharmacy System has been tested prior to initial use and on a periodic basis at each location to ensure that the Automated Pharmacy System is operating properly.

(2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmacist Care that ensures medication orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacist Care. [1]
   (i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.[2]

(ii) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients[3] shall maintain a video/auditory communication system to provide for effective communication between the patient and the Pharmacist; the video/auditory communication system shall allow for the appropriate exchange of oral and written communication and Patient Counseling; if the video/auditory communication system malfunctions, then all operations of the Automated Pharmacy System shall cease until the system is fully functional.

(3) All policies and procedures must be maintained in the Pharmacy responsible for the Automated Pharmacy System and , if the Automated Pharmacy System is being used at a different location, at that location as well.

(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures[4], to:

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[1] Each state should determine whether or not the Dispensing of a "first dose" or an "emergency dose" may take place without prior order review by a Pharmacist but with appropriate security and patient medication management controls in place.

[2] In order to facilitate communication between the Pharmacy and the site where the Automated Pharmacy System is located, a Pharmacy should provide a toll-free telephone number so that the Pharmacist is accessible at all times the Automated Pharmacy System is operational.

[3] Although an "outpatient" generally refers to a Person who receives Drugs for use outside of an Institutional Facility, the definition of "outpatient" must be defined by each state. For example, although the *Model Act* classifies penal institutions as a type of Institutional Facility and therefore its inmates as inpatients, the Pharmacist is exempt from providing Patient Counseling. However, some states may consider inmates of penal institutions as outpatients and therefore should decide if a video/audio communication system is required in such facilities so that the Pharmacist is able to provide Patient Counseling.

[4] The use of Automated Pharmacy Systems requires written policies and procedures in place prior to installation to ensure safety, accuracy, security, and patient confidentiality and to define access and limits to access to equipment and medications.

(i) prevent unauthorized access;
(ii) comply with federal and state regulations; and
(iii) prevent the illegal use or disclosure of Protected Health Information.

(5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
(i) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
(ii) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
(A) identity of 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; and
(F) such additional information as the Pharmacist-in-Charge may deem necessary.

(6) Access to and limits on access (eg, security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations. [5]

(7) The Pharmacist-in-Charge shall have the responsibility to:
(i) assign, discontinue, or change access to the system;
(ii) ensure that access to the medications comply with state and federal regulations;
(iii) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.

(8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.

(9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.[6]

(10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with federal and state laws and regulations.

(11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the

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[5] This section anticipates that decisions regarding which health care professionals may access the Automated Pharmacy System and the level of access allowed (eg, access to medications, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the Automated Pharmacy System; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.

[6] This section anticipates that states will allow non-Pharmacist personnel to fill/stock Automated Pharmacy Systems under a Pharmacist's supervision; however, the state may decide to only allow a Pharmacist to perform this function. Should the State allow non-Pharmacist personnel to perform this function, it should define the level of Pharmacist supervision necessary (eg, immediate, direct, or general).

Automated Pharmacy System, all in accordance with existing state and federal law.[7]

(13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

"Vending" Dispensing Systems

Iowa Rule

7.12(4) Use of InstyMeds dispensing system. A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Persons with access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

c. The dispensing machine shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs "a" through "g."

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's caregiver a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

h. The pharmacy shall, in conjunction with the hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system has been positively identified.

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity

[7] The State may require that each licensed Pharmacy or facility have in place written policies and procedures to address situations in which medications removed from the system remain unused and must be secured and accounted for.

greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

Definitions
"Patient counseling" means a discussion of matters which will enhance or optimize drug therapy.

Subchapter I — General

7.01 Managing Pharmacist.

7.02 Prescription (1) REQUIREMENTS. (a) A prescription drug order shall include all of the following:

1. Date of issue
2. Name and address of the practitioner.
3. Prescriptions written by a delegate of the practitioner shall include the name and signature of the delegate and the name and address of the practitioner.
4. Name, strength, dosage, form and quantity of the drug.
5. Directions for use of the drug.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), the name and address of the authorized entity.
10. Practitioner's written signature, or electronic or digital signature.

(b) A prescription drug order must be communicated to a pharmacist, or when recorded in such a way that the pharmacist may review the prescription drug order as transmitted.

(2) STANDING ORDER. (a) A prescription standing order shall include all of the following:

1. Date of issue
2. Name and address of the practitioner.
3. Prescriptions written by a delegate of the practitioner shall include the name and signature of the delegate and the name and address of the practitioner.
4. Name, strength, dosage, form and quantity of the drug.
5. Directions for use of the drug.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), the name and address of the authorized entity.
10. Indicate the prescription is pursuant to a standing order.

(b) A copy of the standing order shall be retained.

(3) ELECTRONIC PRESCRIPTION. (a) 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.

(b) 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:

1. 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.

2. 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.

3. Contains all other information that is required in a prescription order.

(c) 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.

(d) Any alterations in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration.

(4) ORAL PRESCRIPTION. Oral prescription orders may be received at a pharmacy via a telephone answering device or voice mail. The oral prescription shall be reduced to writing.

7.03 Drug utilization review. (1) A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

(a) Known allergies.

(b) Rational therapy contraindications.

(c) Proper dose, duration of use, and route of administration, considering the age, gender, and other patient factors.

(d) Proper directions for use.

(e) Potential or actual adverse drug reactions.

(f) Drug to drug interactions.

(g) Drug to food interactions.

(h) Drug to disease contraindications.

(i) Therapeutic duplication;

(j) Proper utilization and optimum therapeutic outcomes.

(k) Potential abuse or misuse.

(2) Upon recognizing any of the items in sub. (1) (a) to (k), the pharmacist shall take steps to avoid or resolve the problem.

7.04 Transferring 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 in one of the following ways:

1. Verbal communication between two pharmacists.

2. Electronically or by facsimile machine with the transfer pharmacist authenticating the information being transferred and the receiving pharmacist initiating verbal communication only if there are questions. The act of transfer may be delegated.

(b) The pharmacist receiving the verbal transfer of prescription order information for either a controlled or a non-controlled substance transcribes the transferred information in writing.

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

(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, or delegate, making the transfer records the following information:

1. The word “VOID" is 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 7.10(1) (a) 1. and 2.
2. The name and address of the pharmacy to which it was transferred, the full 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).

(b) The pharmacist, or delegate, receiving the transferred prescription order information shall record the following:

1. The word “TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.
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 or total quantity 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 full name of the pharmacist authorizing the transfer.

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

(a) The requirements in sub. (2).

(b) 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.

(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.
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.

(4) Use of computer system. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.10(1) (a) 1. and 2., contain a shared real time electronic file database with complete prescription record filled and dispensed.

Phar 7.05 Prescription Renewal. (1) A pharmacist shall receive, when required by law and standard professional practice, permission to renew form authorized prescribers, and note of the prescription order, medication profile record or uniformly maintained

(2) No prescription order containing either specific or PRN renewal authorization is valid after the patient-prescriber relationship has ceased.

Phar 7.06 Label Requirements (1) In this section, ambulatory patient does not include those in a correctional facility.

(2) All prescribed drugs or devices for outpatient, ambulatory patient or inpatient self-administration shall have a label attached to the container disclosing all of the following:

(a) Critical information for patients which shall be displayed in a field size and text size which is in the best interest of patient care and includes all of the following:

1. Identification of the patient by one of the following:

a. Except as provided in subd. 1. b to e., the full name of the patient

b. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the full name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".

c. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the name of the person to whom the opioid antagonist is delivered.

d. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), the name of the school, authorized entity, or other person specified under s. 255.07 (3).

e. If the patient is an animal the last name of the owner, name of the animal and animal species.

2. Directions for use as indicated by the prescriber using numeric instead of alphabetic characters for numbers and simplified language.

3. Symptom or purpose if the patient indicates in writing to the prescriber that the patient wants the information on the label.

4. Drug name.

5. Drug strength.

6. The use by date indicating the date after which the medication shall not be used.

(b) Important information for patients which shall not displace the critical information for patients includes all of the following:

1. Pharmacy name.
2. Pharmacy telephone number.
3. Prescriber name.
4. Date the prescription was filled.
5. Prescription number.
6. Drug quantity.
7. Number of remaining refills.
8. Written or graphic product descriptions.
9. Any cautions or other provisions.

(3) Subs. (2) does not apply to complimentary samples of drug products or devices dispensed by a practitioner to his or her patients.

Phar 7.07 Unit of Use Packaging. A Pharmacy prepackaging drugs shall do all of the following:

(1) The prepackaging processes are conducted under conditions that ensure the integrity of the drug.

(2) In the absence of stability data for the drug product in the repackaged container, the beyond-use dating period is one year or the time remaining until the expiration date, whichever is shorter. If current stability data is available for the drug product in the repackaged container, the length of time established by the stability study may be used to establish the beyond use date, but may not exceed the manufacturer's expiration date.

(3) The repackaged container shall meet or exceed the original container's specification for light resistance.

(4) The conditions or storage shall meet the storage specifications as described in the labeling of the original container received for repackaging. Where no specific storage conditions are specified, the product must be maintained at controlled room temperature and in a dry place during the repackaging process, including storage.

(5) The prepackaged drugs are labeled with all the following components:

(a) Drug name, strength and dosage form.

(b) Pharmacy control and manufacturer lot number.

(c) Name of the manufacturer or distributor of the drug or NDC number.

(d) Beyond use date.

(6) Records of all prepackaging operations are maintained and include all the following:

(a) Name, strength, dosage form, quantity per container, and quantity of containers of the drug being prepackaged.

(b) Name of the manufacturer or distributor of the drug or NDC number.

(c) Pharmacy control and manufacturer lot number.

(d) Expiration date of the drug according to the original manufacturer or distributor container and the beyond-use date.

(e) Name, initials, or identification codes of the pharmacist or technician that prepackaged the drug and the name or initials of the pharmacist that verified the appropriateness of the prepackaged drug.

(f) Date the drug is prepackaged.

Phar 7.08 Final Check (1) The final check on the accuracy and correctness of the prescription including all of the following:

(a) Label requirements.

(b) Correct product.

(c) Correct directions.

(d) Ensure completion of the drug utilization review.

(2) For all original and renewed prescriptions, the prescription order record shall identify the pharmacist responsible for the final check of the prescription.

Phar 7.09 Patient Counseling. (1) Patient counseling shall include at least one of the following:

(a) Name and description of the drug.

(b) Dosage form, dose, route of administration and duration for drug therapy.

(c) Intended use of the drug and expected action.

(d) Special directions and precautions for preparation, administration and use by the patient.

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(f) Techniques for self-monitoring drug therapy.

(g) Proper storage and appropriate disposal method of unwanted or unused medication.

(i) Action to be taken in the event of a missed dose.

(j) Assessment of the drug's effectiveness in meeting the patient's treatment goals and any adverse effects related to the prescription.

(2) A pharmacist shall give the patient or patient's agent appropriate consultation relative to the prescription for all new or renewal of a prescription, change in the patient's therapy, and the first refill after a new prescription or change in patient's therapy. The consultation shall occur before the transfer of the drug to the patient. This requirement is not satisfied by only offering to provide consultation.

(3) Sub. (2) applies regardless of the method of delivery of the drug.

(4) Consultation is required upon patient request.

(5) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.

(6) Notwithstanding sub. (2), a consultation is not required when a health care provider is administering the medication.

Phar 7.10 Procurement, recall and out-of-date prescription drugs and devices.

(1) Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board or U.S. food and drug administration to distribute to pharmacies or from another licensed pharmacy or licensed practitioner located in the United States.

(2) There shall be a system for identifying any prescription drugs and devices subjected to a product recall and for taking appropriate steps as required by the recall notice.

(3) Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

[*NOTE Move the storage provision to Phar 6. "(3) Drugs and devices shall be stored in a manner to protect their identity and integrity until delivered or administered."*]

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

(c) "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) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their beyond use date.

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

(c) 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) (a) and (b), 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 of a health care item if a patient or agent of a patient delivers 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 is 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 of a health care item if a patient or agent of a patient delivers 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.

Phar 7.12 Pharmacy Records. (1) PRESCRIPTION RECORDS. (a) 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:

1. Is capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining.
2. 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.

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

(c) All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system.

(d) Electronic prescription records may be maintained instead of paper records if the prescription is scanned into the record.

(2) MEDICATION PROFILE RECORD SYSTEM. (a) An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or renewal, are dispensed. This section does not apply to prescriptions which are administered in a health care facility. The system shall be capable of permitting the retrieval of information. The system need not be limited to individual medication profile records.

(b) The following minimum information shall be retrievable:

1. Full patient name, or if not human name of pet, species and last name of owner.
2. Address of the patient.
3. Birth date of the patient or if not human birthdate of the owner.
4. Name of the drug product dispensed.
5. Strength of the drug product dispensed.
6. Dosage form of the drug product dispensed.
7. Quantity of the drug product dispensed.
8. Directions for use.
9. Prescription identification number or institution unit number

10. Date of all instances of dispensing, for original and renewal prescriptions.
11. Prescriber NPI.

(c) 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.

(d) 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.

(e) Medication profile records shall be maintained for a period of not less than 5 years following the date of the last entry.

Phar 7.13 Delegation by a Physician. The pharmacist shall document the delegation. The delegated act may be started prior to the documentation. Documentation of the delegated act may be in a contract or agreement.

Subchapter II — Central Fill

7.20 Definitions. In this section:

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

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

7.21 Requirements. 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:

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of s. Phar 7.08.

(6) 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.

(7) 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.
(8) 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.
(9) 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.
(10) 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.
(11) 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.
(12) 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.

Subchapter III — Remote Dispensing and Automated Dispensing Systems

Subchapter IV — Institutional Pharmacies

Phar 7.40 Definitions. In this subchapter:
(1) "Chart order" means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or delegate for a drug or device
(2) "Institutional facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other placed licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.
(3) "Institutional pharmacy" means a pharmacy that provides pharmacy services to an institutional facility.

Phar 7.41 Chart orders. A chart order shall contain all of the following:
(1) Full name of the patient.
(2) Date of issuance.
(3) Name, strength, and dosage form of the drug prescribed.
(4) Directions for use.
(5) Practitioner's written signature, or electronic or digital signature.
(6) Prescriptions written by a delegate of the practitioner shall include the name and signature of the delegate and the name of the practitioner.

Phar 7.42 Labels. All prescribed drugs and devices for prescriptions or devices for use by inpatients of a hospital, or health care facility shall have a label attached to the container disclosing all of the following:
(1) Patient's legal name.

(2) Drug name.
(3) Route of administration, if not oral.
(4) Drug Strength.
(5) Prescriber name.
(6) Date of dispensing.
(7) Dispensing pharmacy.
(8) If the drug was repackaged, the name of the person who repackaged it.
(9) Special storage conditions, if required.

Phar 7.43 Cabinets. (1) Arrangements shall be made in advance by the managing pharmacist for a provision of drugs to the health care staff of the institutional facility by use of night cabinets.
(2) In the absence of a pharmacist, drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons.
(3) The managing pharmacist shall develop inventory listings of those drugs to be included in the cabinet, determine who may have access and have systems in place to prevent diversion.

7.44 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 a reason under Phar 7.10 (2) or 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) 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.

(3) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (b), 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.

Subchapter V — Unlicensed Persons

7.50 Direct Supervision. (1) A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats. is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

(2) Direct supervision is

7.51 Unlicensed Persons (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats.

(2) A pharmacist shall provide general supervision of unlicensed personnel. A pharmacist shall be available to the unlicensed person for consultation either in person or contact by telecommunication means.

(3) An unlicensed person may not perform any of the following:

(a) Provide the final verification for the accuracy, validity, completeness of a filled prescription or medication order unless the person is validated for technician-check-technician.

(b) Perform any of the following tasks:

1. Complete the drug utilization review under Phar 7.03.
2. Administer any prescribed drug products, devices or vaccines

(c) Provide patient counseling or consultation.

(4) The prohibitions do not apply in sub. (2), do not apply to a person completing an internship under ch. Phar 17 for purposes of meeting the internship requirement under s. 450.03 (2) (b).

(5) A pharmacist who delegates to an unlicensed person shall first provide training to or verify competency of the person in performing the delegated act.

(6) The pharmacy shall maintain records of delegated acts by pharmacists to unlicensed persons. This record shall be provided to the board upon request.

[Tech-check-tech provisions will be added here.]