



**PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD**

Room 121A, 1400 East Washington Avenue, Madison, WI 53703
Contact: Dan Williams (608) 266-2112
May 25, 2016

*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 (2-8)**
 - 1) Phar 7.10 Relating to Administration of Drug Products (Act 290)
 - 2) Phar 7 Relating to Practice of Pharmacy
 - 3) Update on Legislation and Pending or Possible Rulemaking Projects
- C. Public Comments**

ADJOURNMENT

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 16 May 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Rules Committee			
4) Meeting Date: 25 May 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. Phar 7.10 Relating to Administration of Drug Products (Act 290) 2. Phar 7 Relating to Practice of Pharmacy 3. Update on Pending or Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>16 May 2016</i>	
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.			

TEXT OF RULE

SECTION 1. Phar 7.10 is amended to read:

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

- (1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education, or the board, ~~in injection administration techniques,~~ emergency procedures, and record keeping.
- (2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration ~~by injection~~ of prescribed drug products or devices in an amount that is not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.
- (3) The pharmacist has written procedures regarding the administration ~~by injection~~ of a prescribed drug product or device ~~in the course of teaching self-administration techniques to a patient.~~
- (4) After the pharmacist administers a prescribed drug product or device, the pharmacist shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

SECTION 2. EFFECTIVE DATE. Pursuant to s. 227.24 (1) (c), Stats., these rules shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Phar 7 – Pharmacy Practice

SUBCHAPTER I PHARMACY PRACTICE

Minimum Procedures for Compounding and Dispensing
Prescription Drug Processing
Managing Pharmacist
Pharmacy Technicians/Training and Utilization of Technicians and Support Persons
Patient Counseling
Delivery
Pharmacist Care
Valid Prescriber/Patient Relationship
Prospective Drug Use Review
Prescription Orders Transmitted Electronically
Transfer of Prescriptions
Prescription Label; Name of Drug or Drug Product Dispensed
Prescription Renewal Limitations
Procurement, Storage and Recall of Drugs and Devices
Drug Identification
Out of Date Drugs and Devices/ Pharmaceuticals Beyond Use Dates
Prepackaging
Return or Exchange of Health Items
Prescription Records; Patient Records
Medication Profile Record System
Confidential Information
Collaborative Drug Therapy Management
Administration of Vaccines
Administration of Drug Products and Devices Other Than Vaccines
Answering Machines in Pharmacies; Electronic Prescriptions
Automated Dispensing Systems; Automated Pharmacy Services
Operation of Remote Dispensing Sites
Central Fill Pharmacy
Telepharmacy
Quality Improvement
Pilot Programs

SUBCHAPTER II HOSPITAL PHARMACY PRACTICE

Tech-Check-Tech

SUBCHAPTER III LONG TERM CARE PHARMACY PRACTICE

SUBCHAPTER IV CORRECTIONAL PHARMACY PRACTICE

Return or Exchange of Health Items

SUBCHAPTER V CARE OUTSIDE OF THE PHARMACY PRACTICE

SUBCHAPTER VI NUCLEAR PHARMACY PRACTICE

Managing Pharmacist

450.09(1) MANAGING PHARMACIST (a) Every pharmacy shall be under the control of the managing pharmacist who signed the pharmacy license application, the most recent license renewal application or the most recent amended schedule of operations. The managing pharmacist shall be responsible for the professional operations of the pharmacy. A pharmacist may be the managing pharmacist of not more than one community and one institutional pharmacy at any time and shall be engaged in the practice of pharmacy at each location he or she supervises. The board shall be rule define community pharmacy and institutional pharmacy for the purposes of this section.

(b) If the managing pharmacist anticipates being continuously absent for a period of more than 30 days from a pharmacy he or she supervises, the managing pharmacist shall delegate the supervisory responsibility to another pharmacist for the duration of the absence by written power of attorney which shall be kept on file in the pharmacy to which the power of attorney applies. The pharmacist designated to assume the supervisory responsibility for the pharmacy during the managing pharmacist's absence shall be engaged in the practice of pharmacy at the pharmacy to which the power of attorney applies.

NABP

Duties and Responsibilities of the Pharmacist-in-Charge

- (1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.
- (2) The Pharmacist-in-Charge has the following responsibilities:
 - (i) Developing or adopting, implementing, and maintaining:
 - (A) Policies and procedures addressing the following:
 - (-a-) the provision of Pharmacy services;
 - (-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern;
 - (-c-) computerized recordkeeping systems;
 - (-d-) Automated Pharmacy Systems;
 - (-e-) preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;
 - (-f-) operation of the Pharmacy in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed. Such policies and procedures shall include reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence;
 - (-g-) the proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug product(s) have been Dispensed;
 - (-h-) the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.
 - (-i-) actions to be taken to prevent and react to pharmacy robberies and thefts, including but not limited to coordinating with law enforcement, training, mitigation of harm, and protecting the crime scene.
 - (-j-) the PIC shall have policies and procedures in place that restrict and monitor control over and access to the locks, barriers, and systems used to

- secure the pharmacy and pharmacy systems in accordance with state laws and regulations.
- (B) Policies and procedures that address the following activities related to prescription medication shipment by mail or common carrier:
 - (-a-) properly transferring prescription information to an alternative Pharmacy of the patient's choice in situations where the medication is not Delivered or Deliverable;
 - (-b-) verifying that common carriers have in place security provisions, such as criminal background checks and random drug screens on its employees who have access to prescription medications;
 - (-c-) tracking all shipments; and
 - (-d-) ensuring that Drugs do not become adulterated in transit
 - (C) Quality assurance programs addressing the following:
 - (-a-) Pharmacy services. The quality assurance program should be designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;
 - (-b-) Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed, while maintaining appropriate record keeping and security safeguards; and;
 - (-c-) The prevention and detection of Drug diversion.
- (ii) Ensuring that:
- (A) all Pharmacists and Pharmacy Interns employed at the Pharmacy are currently licensed and that all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates employed at the Pharmacy are currently registered with the Board of Pharmacy.
- (iii) Notifying the Board of Pharmacy, immediately and in writing, of any of the following changes:
- (A) change of employment or responsibility as the Pharmacist-in-Charge;
 - (B) the separation of employment of any Pharmacist, Pharmacy Intern, Certified Pharmacy Technician Candidate, or Certified Pharmacy Technician for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall notify the Board of Pharmacy;
 - (C) change of ownership of the Pharmacy;
 - (D) change of address of the Pharmacy;
 - (E) permanent closing of the Pharmacy;
 - (F) Significant Quality-Related Events;
 - (G) the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:
 - (-a-) the name and address of the Pharmacy;
 - (-b-) the location of the Automated Pharmacy System; and

- (-c-) the identification of the responsible Pharmacist.
 - (-d-) Such notice must be must occur prior to the installation or removal of the system.
 - (iv) Making or filing any reports required by state or federal laws and rules.
 - (v) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board of Pharmacy and as required by Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.
 - (vi) Responding to the Board of Pharmacy regarding any minor violations brought to his or her attention.
- (3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates as may be required to competently and safely provide Pharmacy services.
- (i) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates assisting in the provision of Pharmacy services.
 - (ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.
 - (iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a Certified Pharmacy Technician training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall utilize a Certified Pharmacy Technician training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates successfully completing a site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board.