



PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison, WI 53705
Contact: Tom Ryan (608) 266-2112
October 25, 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 (2-4)**
 - 1) Phar 6 Relating to Storage
 - 2) Phar 7 Relating to Current Pilot Programs
 - 3) Phar 7 Relating to the Practice of Pharmacy
- C. Public Comments**

ADJOURNMENT

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: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 15 October 2018 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 October 2018	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 6 Relating to Storage 2. Phar 7 Relating to Current Pilot Programs 3. Phar 7 Relating to the Practice of Pharmacy	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <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>			
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.			

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

Phar 6.01	Licenses; application.	Phar 6.06	Laws and other references.
Phar 6.02	Licenses; change of location or ownership.	Phar 6.07	Storage.
Phar 6.03	Changes in managing pharmacist.	Phar 6.075	Temperature; Humidity.
Phar 6.04	Floor design.	Phar 6.08	Security.
Phar 6.05	Sanitation.		

Note: Chapter Phar 6 as it existed on January 31, 1983, was repealed and a new chapter Phar 6 was created effective February 1, 1983.

Phar 6.01 Licenses; application. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

Note: Applications are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, January, 1989, No. 397; am. Register, August, 1991, No. 428, eff. 9-1-91; am., Register, December, 1998, No. 516, eff. 1-1-99; correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

Phar 6.02 Licenses; change of location or ownership. (1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

(1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner returned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; cr. (1m), Register, February, 1996, No. 482, eff. 3-1-96.

Phar 6.03 Changes in managing pharmacist. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

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

Phar 6.04 Floor design. (1) PROFESSIONAL SERVICE AREA. The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present, the professional service area shall be secured as specified in sub. (3). A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service area plan varies from the requirement.

(2) PRESCRIPTION COUNTER SPACE. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free-working surface must be used only for the compounding and dispensing of prescriptions.

(3) PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT. (a) Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if the following requirements are met:

1. A secured, physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unlicensed personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

2. The barrier is locked in the absence of the pharmacist.

3. A patient's telephone request to renew a certain prescription may be accepted, but a telephone message from a practitioner giving a new prescription order or renewal authority may not be accepted.

5. Signs of reasonable size are posted at the entrance of the building and the professional service area prominently displaying the hours the pharmacist will be on duty.

6. The manner in which the telephone is answered does not imply that the location is, at that time, operating as a pharmacy.

7. The pharmacy examining board office is notified of the hours during which the establishment is operated as a sundry outlet.

(b) The managing pharmacist is responsible for compliance with all professional service area security requirements.

(c) Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:

1. The pharmacist is absent for a time period of one half hour or less.

2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager or other device.

3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.

4. Pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2).

(4) PROFESSIONAL SERVICE AREA REMODELING. Any modifications of the approved floor plan shall be submitted to and approved by the board or its designee. Board action must be taken within 60 days.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; cr. (4), Register, August, 1991, No. 428, eff. 9-1-91; r. (3) (a) 4., Register, January, 1996, No. 481, eff. 2-1-96; CR 03-096: am. (3) (a) (intro.), cr. (3) (c) Register May 2004 No. 581, eff. 6-1-04.

Phar 6.05 Sanitation. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning

pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

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

Phar 6.06 Laws and other references. The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice and shall have all of the following:

(1j) The latest available or immediately accessible version of federal and state pharmacy laws consisting of:

(a) Drug enforcement administration regulations, 21 CFR 1300 to end.

(b) Wisconsin pharmacy laws, ch. 450, Stats.

(c) Wisconsin controlled substances act, ch. 961, Stats.

(d) Wisconsin administrative code, rules of the pharmacy examining board.

(2k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(3L) The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; r. and recr. Register, January, 1989, No. 397, eff. 2-1-89; correction in (2) made under 13.93 (2m) (b) 6., Stats., Register, January, 1989, No. 397; am. (1) (j) 3., Register, December, 1998, No. 516, eff. 1-1-99; CR 01-023: am. (1) (intro.) and (a) to (c), (j) (intro.) and (k), Register, August 2001 No. 548 eff. 9-1-01; 2017 Wis. Act 18: r. and recr. (title), renum. (1) (intro.) to (intro.) and am., r. (1) (a) to (i), renum. (1) (j), (k), (L) to (1j), (2k), (3L), r. (2) Register June 2017 No. 738, eff. 7-1-17.

Phar 6.07 Storage. (1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

(2) The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

(3) Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

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

Phar 6.075 Temperature; Humidity. (1) DEFINITIONS. In this section:

(a) "Business day" means a day the pharmacy is open for business.

(b) "Dry place" means a place that does not exceed 40% average relative humidity at 68 degrees Fahrenheit or the equivalent water vapor pressure at other temperatures.

(c) "Freezer" means a place in which the temperature is maintained between -13 and +14 degrees Fahrenheit.

(d) "Mean kinetic temperature" means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

(e) "Refrigerator" means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place, according to the manufacturer recommendation or an official pharmaceutical compendium.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature over the course of the time a pharmacy is closed shall be obtained.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgment, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

History: CR 16-073: cr. Register November 2017 No. 743, eff. 12-1-17; corrections in (1) (b) and (c), (6) made under s. 35.17, Stats., Register November 2017 No. 743.

Phar 6.08 Security. A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99; CR 05-001: am. Register August 2005 No. 596, eff. 9-1-05; CR 09-098: am. Register May 2010 No. 653, eff. 6-1-10.