

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING :
PROCEEDINGS BEFORE THE : NOTICE OF PUBLIC HEARING
PHARMACY EXAMINING BOARD :

NOTICE IS HEREBY GIVEN that pursuant to authority vested in the Pharmacy Examining Board in ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3) (a), (b), (d) and (e), Stats., and interpreting ss. 450.02 (3) (b), 450.06 (2) (b), 450.09 (3) and 450.11 (1) and (2), Stats, the Pharmacy Examining Board will hold a public hearing at the time and place indicated below to consider an order to amend Phar 6.08, 7.12 (2) (f) and 8.12 (2) (b), relating to security systems, utilization reviews, and prescription orders transmitted by facsimile.

Hearing Date, Time and Location

Date: December 2, 2009
Time: 9:30 a.m.
Location: 1400 East Washington Avenue
(Enter at 55 North Dickinson Street)
Room 121A
Madison, Wisconsin

APPEARANCES AT THE HEARING:

Interested persons are invited to present information at the hearing. Persons appearing may make an oral presentation but are urged to submit facts, opinions and argument in writing as well. Facts, opinions and argument may also be submitted in writing without a personal appearance by mail addressed to the Department of Regulation and Licensing, Division of Board Services, P.O. Box 8935, Madison, Wisconsin 53708. Written comments must be received by December 2, 2009, to be included in the record of rule-making proceedings.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:

Sections 450.02 (3) (b), 450.06 (2) (b), 450.09 (3) and 450.11 (1) and (2), Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) and 450.02 (3) (a), (b), (d) and (e), Stats.

Explanation of agency authority:

The Pharmacy Examining Board has the authority under s.450.02 (3) (d), Stats., to promulgate rules necessary for the administration of ch. 450, Stats., and under s. 450.02 (3) (a) to (c), Stats., relating to the distribution and dispensing of drugs; establishment of security standards for pharmacies, and establishment of minimum standards for the practice of pharmacy.

Related statute or rule:

There are no other statutes or rules other than those listed above.

Plain language analysis:

SECTION 1 amends s. Phar 6.08 to clarify that a pharmacy is required to have a centrally monitored alarm system. The current rules permit a pharmacy to have an alarm system in the immediate physical structure within which a pharmacy is located.

SECTION 2 amends s. Phar 7.12 (2) (f) to clarify that the reference to “drug initialization” used in the rule should read “drug utilization.”

SECTION 3 amends s. Phar 8.12 (2) (b) to clarify that prescription orders may be transmitted by a facsimile machine in instances in which a patient “meets the eligibility requirements for placement in a long term care facility,” but elects to reside at home. Under the current rules a pharmacist may not dispense a schedule II controlled substance pursuant to a prescription order transmitted by a facsimile machine unless certain conditions stated in s. Phar 8.12 (1) are satisfied and all the conditions set forth in s. Phar 8.12 (2) (a) to (c) are met.

Summary of, and comparison with, existing or proposed federal regulation:

There is no existing or proposed federal regulation.

Comparison with rules in adjacent states:

Illinois:

Pharmacy Alarms, Security.

Section 1330.75 Security Requirements. a) Whenever the pharmacy (prescription area) is not occupied by a registrant, the pharmacy (prescription area) must be secured and inaccessible to non-licensed persons (employees and public). This may be accomplished by measures such as walling off, locking doors, and electronic security equipment, as approved by the Division.

Utilization Review. Not applicable. Rule corrects a drafting error.

Faxing Schedule II Controlled Substance Prescriptions.

Neither the statutes nor rules establish prima facie permission for pharmacists to dispense schedule II controlled substances faxed by a practitioner on behalf of patients residing in-home that are eligible for nursing home placement.

Iowa:

Pharmacy Alarms, Security.

657—6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657—Chapter 21.

6.7(1) Department locked. The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.7(2).

6.7(2) Temporary absence of pharmacist. In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons who may be present in the prescription department to perform technical and nontechnical functions designated by the pharmacist in charge.

Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

8.5(3) Secure barrier. The pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be 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 prior to the start of construction. The board may also require on-site inspection of the facility or pharmacy department prior to the pharmacy's opening or relocation. The pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A). [4/4/2007]

Utilization Review. Not applicable. Rule corrects a drafting error.

Faxing Schedule II Controlled Substance Prescriptions.

Neither the statutes nor rules establish prima facie permission for pharmacists to dispense schedule II controlled substances faxed by a practitioner on behalf of patients residing in-home that are eligible for nursing home placement.

Michigan:

Pharmacy Alarms, Security.

R 338.482 Housing of pharmacy.

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee shall be permanently enclosed by partitions from the floor to the ceiling. All partitions shall be of substantial construction and shall be securely lockable so that drugs and devices that can only be sold by a pharmacist are unobtainable during the absence of the pharmacist. Identification of this department by the use of the words “drug,” “medicines,” or “pharmacy” or by the use of a similar term or combination of terms shall be restricted to the area that is registered by the board. The pharmacy department shall be locked when the pharmacist is not in the establishment.

Utilization Review. Not applicable. Rule corrects a drafting error.

Faxing Schedule II Controlled Substance Prescriptions.

Neither the statutes nor rules establish prima facie permission for pharmacists to dispense schedule II controlled substances faxed by a practitioner on behalf of patients residing in-home that are eligible for nursing home placement.

Minnesota:

Pharmacy Alarms, Security.

6800.0700 PHARMACY, SPACE, AND SECURITY.

Subpart 1 D. The pharmacy must be surrounded by a continuous partition or wall extending from the floor to the permanent ceiling, containing doors capable of being securely locked to prevent entry when the pharmacy is closed.

Utilization Review. Not applicable. Rule corrects a drafting error.

Faxing Schedule II Controlled Substance Prescriptions.

Neither the statutes nor rules establish prima facie permission for pharmacists to dispense schedule II controlled substances faxed by a practitioner on behalf of patients residing in-home that are eligible for nursing home placement.

Summary of factual data and analytical methodologies:

The board recognized the need to tighten security requirements so that all pharmacies, even if they are located within a larger structure that is alarmed, would be equipped with an alarm. The board was contacted about the barriers to providing care to long term pharmacy care patients

who receive care at home. As a result of a subsequent discussion during a board meeting, the board decided to change its controlled substances faxing rule.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report:

Requiring all pharmacies to be alarmed may have an impact on small businesses, but its primary impact is on chain or hospital pharmacies that are more typically inside a larger structure. The faxing change will assist small businesses in providing care to long term care patients at home.

Section 227.137, Stats., requires an “agency” to prepare an economic impact report before submitting the proposed rule-making order to the Wisconsin Legislative Council. The Department of Regulation and Licensing is not included as an “agency” in this section.

Anticipated costs incurred by private sector:

The department finds that this rule has no significant fiscal effect on the private sector.

Fiscal estimate:

The department estimates that this rule will require staff time in the Division of Professional Credentialing. The total one-time salary and fringe costs are estimated at \$266.

Effect on small business:

These proposed rules were reviewed and discussed by the department’s Small Business Review Advisory Committee which determined that the rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at hector.colon@wisconsin.gov, or by calling 608-266-8608.

Agency contact person:

Pamela Haack, Paralegal, Department of Regulation and Licensing, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-266-0495; email at pamela.haack@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Pamela Haack, Paralegal, Department of Regulation and Licensing, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708-8935, or by email to pamela.haack@wisconsin.gov. Comments must be received on or before December 2, 2009, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 6.08 is amended to read:

Phar 6.08 Security. A pharmacy shall have a centrally monitored alarm system in the pharmacy ~~or the immediate physical structure within which the pharmacy is located~~. 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.

SECTION 2. Phar 7.12 (2) (f) is amended to read:

Phar 7.12 (2) (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 ~~initialization~~ utilization review, refill authorizations, interventions and drug interactions.

SECTION 3. Phar 8.12 (2) (b) is amended to read:

Phar 8.12 (2) (b) The prescription order is written for a schedule II controlled substance for a patient who resides in a long term care facility, or who meets the eligibility requirements for placement in a long term care facility but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

COPIES OF RULE

Copies of this proposed rule are available upon request to Pamela Haack, Paralegal, Department of Regulation and Licensing, Division of Board Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708, or by email at pamela.haack@wisconsin.gov.

Phar 6.08, 7.12, 8.12 (Security, utilization review, faxing) Hearing Notice 10-29-09