

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), 450.02 (3) (d) and 450.062, Stats., and interpreting ss. 450.06 (1) and 450.062, Stats., the Pharmacy Examining Board will hold a public hearing at the time and place indicated below to consider an order to create Phar 7.095, relating to remote dispensing sites.

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 450.06 (1) and 450.062, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2), 450.02 (3) (d) and 450.062, Stats.

Explanation of agency authority:

The board is authorized under s. 450.02 (3) (d), Stats., to promulgate rules necessary for the administration of ch. 450, Stats., and under s. 450.062, Stats., to promulgate rules relating to the establishment and operation of remote dispensing sites.

Related statute or rule:

Section Phar 7.09 relates to the use of automated dispensing systems.

Plain language analysis:

SECTION 1 creates s. Phar 7.095, which sets forth the process and procedures for establishing and operating remote dispensing sites.

As stated in s. 450.06 (1), Stats., except as provided in rules adopted by the board under s. 450.062, Stats., no pharmacist may dispense at any location that is not licensed as a pharmacy by the board. The board is proposing to adopt these rules to set forth the process and procedures for establishing and operating remote dispensing sites.

The proposed rules include definitions for “health care facility,” “managing pharmacist,” “practitioner,” “remote dispensing site,” and “supervising pharmacy.” The proposed rules also clarify that a remote dispensing site shall not be licensed as a pharmacy and that no person may use or display certain titles in connection with the operation of a remote dispensing site. In addition, the proposed rules identify where remote dispensing sites may be located; the requirements for operating remote dispensing sites; the requirements for dispensing; the responsibilities of managing pharmacists, and the requirements for pharmacy technicians and interns.

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:

Statutes: Section 225 ILCS 85

Rules: Section 1330.98

Illinois’ statutes provide a significant amount of detail as to tele-pharmacy, remote prescription processing, common electronic filing, automated dispensing and storage systems, and centralized prescription filling. Tele-pharmacy is included as part of the definition of the practice of pharmacy. Tele-pharmacy models must meet a set of conditions regarding pharmacist responsibility, technician training, supervision and patient counseling. Remote prescription processing, or “outsourcing” occurs when at least one of eight listed functions are identified.

Conditions under which remote prescription processing may occur are also specified, including ownership, electronic filing and record maintenance provisions. The statutes are very detailed regarding automated pharmacy systems/remote dispensing. Subjects covered include: security; procedures; confidentiality; designated personnel; storage (temperature, proper containers, handling outdated drugs), dispensing and delivery, home pharmacy supervision and re-stocking of systems that use removable cartridges. The rules provide additional detail for automated dispensing and storage systems, including provisions relating to documentation, storage, security, record keeping, stocking, proper containers, and quality assurance.

Iowa:

Rules: Chapters 9 and 18.

Chapter 9 of Iowa's rules relates to automated medication dispensing systems, including: pharmacist responsibilities; quality assurance; policies and procedures; system, site and process requirements; dispensing and distributing; security and confidentiality; records; error identification and logging; verification and accuracy; reporting; and outpatient automated medication dispensing. Chapter 18 addresses centralized filling and processing, including: system qualifications; labeling; legal compliance; patient notification; originating pharmacy compliance; policies and procedures; and records.

Michigan:

Statutes: Section 333.17753, Michigan Public Health Code

Rules: Chapter 338

Michigan's statutes include a section on centralized prescription filling, which lists the record-keeping, security and quality improvement conditions that apply to outsourcing. The rules state that a license is required at each separate location where drugs are prepared or dispensed.

Minnesota:

Statutes: Section 150.01

Rules: Section 6800.0800, 2600, 4075, 6600

Minnesota's statutes define central service pharmacy as a pharmacy that may provide dispensing functions, drug utilization review, packaging, labeling, or delivery of a prescription product to another pharmacy for the purpose of filling a prescription. Minnesota's rules provide definitions for community and hospital satellite pharmacies. Plans for satellite pharmacies must be submitted to the board for approval. The rules also specify the requirements for vending machines (responsibility, policies and procedures), centralized processing and filling (ownership, filing, policy and procedures manual, records, tracking of drugs, security, quality improvement, counseling and notification), and freedom of choice.

Summary of factual data and analytical methodologies:

The board created a committee to draft remote dispensing guidelines after 2007 Wisconsin Act 202 (Senate Bill 409) became effective. The committee met once and devised several safeguards to protect the public. Since the remote dispensing model departs from the traditional dispensing model, the board sought to address drug security, training and supervision of remote site staff, privacy, labeling and quality assurance in the context of remote site dispensing. The final guidelines, which have been written into this rule draft, are the result of committee discussions and recommendations that were finalized by the full board.

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

This rule will have an impact on small businesses, though it is not clear exactly what impact it will have. The board received correspondence expressing concerns and suggesting that the remote sites will adversely impact chain and independent pharmacies in the region, making it more difficult to compete. One pharmacy owner suggested protective language in the remote dispensing rules that would disallow remote sites within a pre-determined radius of existing pharmacies. The board took up the concerns at its July 22, 2009 meeting and deliberated on the benefits and costs of the legislation, noting that its primary purpose is to increase access to prescription drugs. The board also noted that small business concerns were heard while the legislation was pending, resulting in Amendment 1 to Senate Bill 409, which limited remote dispensing to sites specifically identified in the legislation. It was noted in testimony that there is a likelihood that small businesses will benefit from new ventures with clinics and practitioners. The board also considered other possibilities, such as improved care coordination and the increased likelihood of patients to fill prescriptions at a remote site located at a health clinic.

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 Board Services. The total on-going salary and fringe costs are estimated at \$7,100.

Effect on small business:

These proposed rules were reviewed and discussed by the department’s Small Business Review Advisory Committee which determined that these 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@drl.state.wi.us, or by calling (608) 266-8608.

Agency contact person:

Pamela Haack, Paralegal, Department of Regulation and Licensing, Division of Board Services, 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, Division of Board Services, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, WI 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 7.095 is created to read:

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

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

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

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

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

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

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

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

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

(a) A health care facility under s. 150.84 (2), Stats., or a facility identified under s. 980.065, Stats.

(b) The office or clinic of a practitioner.

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

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

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

1. Prescriptions may be filled at this location.
2. This store is a remote dispensing site being supervised by a pharmacist located at:
 - a. Name of store.
 - b. Address of store.
 - c. Telephone number of store.
3. The pharmacist is required to talk to you each time you pick up a prescription.

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

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

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

(5) DISPENSING REQUIREMENTS. A remote dispensing site shall:

(a) Comply with the requirements under s. Phar 7.01, including visual access of prescription orders, labels and dispensed product.

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

(c) If dispenses controlled substances, comply with federal law.

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

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

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

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

4. The documentation of the monthly inspection visits shall be retained at the remote dispensing site for 2 years.

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

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

(a) Be 18 years of age or older.

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

(c) Have completed 2000 hours of work as a technician within the 3 years prior to the date of employment at the remote dispensing site or completed a training program approved by the board.

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 7.095 (Remote dispensing sites) Hearing Notice 10-29-09