

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 23-054)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d), and 7.61; amend Phar 7.43 (2), (4) (a) 2. (intro.), (4) (b), (5) (b), and (7) (intro.), and 7.62 (1); create Phar 1.02 (3m), (10m), and (14m), 5.01 (4), 6.025, and 8.01 (5); and repeal and recreate Phar 7.43 (6), relating to remote dispensing.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.02 (5) and 450.09 (1) and (2) (b) 2, Stats.

Statutory authority: ss. 15.08 (5) (b); 450.02 (3) (a), (d), and (e), and 450.02 (5), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that “The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.”

Section 450.02 (3) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

Section 450.02 (3) (d), Stats. says that the board “may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.”

Section 450.02 (3) (e), Stats. provides that the board “may promulgate rules establishing minimum standards for the practice of pharmacy.”

Section 450.02 (5), Stats. provides that “the board may promulgate rules governing pharmacies that are operated as remote dispensing sites. Rules promulgated under this subsection may exempt pharmacies operated as remote dispensing sites from requirements governing pharmacies that are not operated as remote dispensing sites.”

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101. These changes include the creation of s. Phar 6.025, which are rules that specifically apply to remote dispensing sites, as well as amendments to s. Phar 7.43 to allow for remote dispensing sites to operate without the presence of a pharmacist. Clarification was also added to ss. Phar 5.01 (4) and 8.01 (5) that pharmacies shall include remote dispensing sites. The Board also added a definition of pharmacy graduates to chapter Phar 1, and modified requirements in chapter Phar 7 to allow them to practice pharmacy while waiting for their license to be granted.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for pharmacy licensure and dispensing. There is a provision that allows a pharmacy that is not in the same location as its home pharmacy, and services are being provided during an emergency situation, to operate as an emergency remote pharmacy. The Illinois Department of Financial and Professional Regulation may also waive the requirement for a pharmacist to be on duty at all times for state facilities that are not treating human ailments. Additionally, automated pharmacy systems operated from a remote site must be under continuous supervision of a pharmacist however, that pharmacist is not required to be physically present if they can monitor the system electronically [225 Illinois Compiled Statutes ch. 85 s. 15 and 22b]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include definitions for “emergency situation” and what is required in order to operate an emergency remote temporary pharmacy [Illinois Administrative Code s. 1330.420].

In Illinois, graduate of a pharmacy program approved by the Illinois Department of Financial and Professional Regulation may be registered as a pharmacy technician with the “student pharmacist” designation, if they have graduated from said program within the last 18 months. Student pharmacists are allowed to practice pharmacy under the supervision of a pharmacist [225 Illinois Compiled Statutes ch. 85 s. 9 (c)].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100 percent of the time and the site must apply for licensure as a general pharmacy [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a “pharmacist-intern.” Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving “licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy,” whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (3)].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Unless at a mental health facility or hospital, remote pharmacies cannot be located within 10 miles of another pharmacy, unless a waiver is granted by the Michigan Board. A pharmacist is required to oversee a remote pharmacy; however, a qualified pharmacy technician must be on site at all times that the pharmacy is open if the pharmacist in charge is not physically present. A Pharmacist may not be responsible for more than three remote pharmacy sites at any one time [Michigan Compiled Laws s. 333.17742a and b].

In Michigan, pharmacy graduates can apply for an educational limited license if they are within 180 days of completing an approved educational program. Pharmacy graduates practicing under an educational limited license may only do so under the “personal charge of a pharmacist” [Michigan Administrative Code R 338.513].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. [Minnesota Administrative Rules part 6800]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations. According to Section 34 (10) of this chapter, it is unlawful to run a pharmacy without a pharmacist in charge. Operation of a pharmacy without a pharmacist present and on duty is only allowed under an approved variance by the Board. [Minnesota Statutes 151.34 (10), 151.071 (2) (13)].

In Minnesota, pharmacy graduates can apply for a “pharmacist-intern” registration if they are a graduate of a pharmacy college approved by the Minnesota Board. Pharmacist interns must practice under the direct supervision of a licensed pharmacist [Minnesota Administrative Rules Chapter 6800 Parts 5100-5600].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 101 and updated Wisconsin Administrative Code Chapters Phar 1, 5, 6, 7, and 8 accordingly. While completing this review, the Board also identified a need to create a definition of a Pharmacy Graduate and include them in certain pharmacy practice circumstances.

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

The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on October 26, 2023, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 1.02 (3m) is created to read:

Phar 1.02 (3m) “Direct supervision” means immediate, whether in person or real time video conferencing where all parties can communicate by simultaneous means of audio, video, or data communications, availability to continually coordinate, direct and inspect in real time the practice of another.

SECTION 2. Phar 1.02 (9) is repealed.

SECTION 3. Phar 1.02 (10m) and (14m) are created to read:

Phar 1.02 (10m) “Pharmacy graduate” means a graduate of a school of pharmacy approved by the board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting examination for licensure approved by the board.

Phar 1.02 (14m) “Remote dispensing site” has the meaning given in s. 450.01 (21c), Stats.

SECTION 4. Phar 5.01 (4) is created to read:

Phar 5.01 (4) For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

SECTION 5. Phar 6.025 is created to read:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules in this section that apply only to remote dispensing sites, if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be met:

- (1) The licensee provides notice to the Board of all of the information outlined in s. 450.06, Stats.
- (2) The site meets all of the requirements listed in s. Phar 7.43.
- (3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.
- (4) A managing pharmacist shall report to the board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist may not be responsible for more than 10 remote dispensing sites at any given time without approval from the board.

SECTION 6. Phar 7.43 (1) is repealed.

SECTION 7. Phar 7.43 (2) is amended to read:

Phar 7.43 (2) LOCATION. A ~~pharmacist or a person engaged in the practice of pharmacy~~ under s. 450.03 (1) (f) or (g), ~~or (i),~~ Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. ~~450.62 (1) to (4)~~ 450.09 (2) (b) 1. a. to d., Stats.

SECTION 8. Phar 7.43 (3) is repealed.

SECTION 9. Phar 7.43 (4) (a) 2. (intro.) and (4) (b) are amended to read:

Phar 7.43 (4) (a) 2. (intro.) This remote dispensing location is being supervised by a pharmacist employed by ~~located at all of the following:~~

Phar 7.43 (4) (b) Remote dispensing may not occur if ~~the supervising pharmacy is closed~~ a pharmacist is not available remotely.

SECTION 10. Phar 7.43 (4) (d) is repealed.

SECTION 11. Phar 7.43 (5) (b) is amended to read:

Phar 7.43 (5) (b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the ~~supervising pharmacy~~ remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

SECTION 12. Phar 7.43 (6) is repealed and recreated to read:

Phar 7.43 (6) RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacy shall do all of the following:

- (a) Have written policies and procedures for system operation, safety, security, accuracy and access.
- (b) 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, and documentation of remedial training to prevent future errors.
- (c) Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.
- (d) Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.
- (e) Documentation indicating accepting responsibility for compliance with this section, signed and dated by the managing pharmacist.

SECTION 13. Phar 7.43 (7) (intro.) is amended to read:

Phar 7.43 (7) (intro.) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), ~~or (i)~~, Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) shall meet the following requirements to remote dispense:

SECTION 14. Phar 7.61 is repealed.

SECTION 15. Phar 7.62 (1) is amended to read:

Phar 7.62 (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m).

SECTION 16. Phar 8.01 (5) is created to read:

Phar 8.01 (5) REMOTE DISPENSING SITES. For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

SECTION 17. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated _____

Agency _____

Chairperson
Pharmacy Examining Board