

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 053-22, was approved by the Governor on June 13, 2022, published in Register 798B on June 27, 2022, and approved by the Pharmacy Examining Board on July 8, 2022. This emergency rule as approved by the Governor on October 6, 2022.

ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

EXEMPTION FROM FINDING OF EMERGENCY

The Legislature by section 14 (1) of 2021 Wisconsin Act 101 provides an exemption from a finding of emergency for the adoption of the rule.

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). Stats, and 2021 Wisconsin Act 101 s. 14 (1)

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.”

2021 Wisconsin Act 101, Section 14 (1) provides: “The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act.

Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this

subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner.”

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.

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.

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].

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)].

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].

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)].

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.

Fiscal Estimate: The Fiscal Estimate will be attached upon completion.

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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-26-7139; 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, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1 Phar 1.02 (9) is repealed.

SECTION 2 Phar 1.02 (14m) is created to read:

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

SECTION 3 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 4 Phar 6.025 is created to read:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules that apply only to remote dispensing sites if no pharmaceutical services is provided at that pharmacy by a pharmacist who is present in the pharmacy, and the following conditions have been 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 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 shall not be responsible for more than 10 remote dispensing sites at any given time without approval from the Board.

SECTION 5 Phar 7.43 (1) is repealed.

SECTION 6 Phar 7.43 (2); (4) (b); (5) (b); (6) (title), (6) (a), (6) (a) 5, and (6) (b) are 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), (g), or (i), Stats., may dispense at any of the locations under s. ~~450.062 (1) to (4)~~ 450.09 (2) (b) 1. a. to d., Stats.

- (4) (b) Remote dispensing may not occur if ~~the supervising pharmacy is closed a~~ pharmacist is not available remotely.
- (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.
- (6) (title) Responsibilities of managing pharmacist ~~or supervising pharmacist.~~
- (6) (a) The managing pharmacist of the supervising pharmacy ~~or the supervising pharmacist~~ shall do all of the following:

~~(6) (a) 5. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end.~~

~~(6) (b) The managing pharmacist at the supervising pharmacy or supervising pharmacist is responsible for all remote dispensing connected to the supervising pharmacy.~~

SECTION 7 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 8 Pursuant to 2021 Wisconsin Act 101 section 14 (1), this emergency rule shall take effect upon publication in the official state newspaper and remain in effect until May 1, 2024 or until the date on which permanent rules take effect, whichever is sooner.

(END OF TEXT OF RULE)