

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check.

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule: The objective of the proposed rule is to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, the definition of a managing pharmacist, initial prescription consultation by a pharmacist, alteration of a prescription, and prescription final check. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Wisconsin Administrative Code Phar 7 includes requirements for the practice of pharmacy. These requirements have the potential to become outdated on a regular basis. If the Board does not make regular updates via the permanent rules process, there will be inconsistencies between current pharmacy practice and what is required in the Wisconsin Administrative Code. This project will ensure that the Wisconsin Administrative Code continues to be current in the practice areas listed above.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

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.”

450.02 (2), Stats., states that “the Board shall promulgate rules that do all of the following:

(a) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

(b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68.”

450.02 (3) (a), Stats., states “[t]he Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

450.02 (3) (b), Stats., states “[t]he Board may promulgate rules establishing security standards for pharmacies.”

450.02 (3) (d), Stats., states “[t]he Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.”

450.02 (3) (e), Stats., states “[t]he Board may promulgate rules establishing minimum standards for the practice of pharmacy.”

450.02 (5), Stats., states “[t]he Board may promulgate rules governing pharmacies that are operated as remote dispensing sites.”

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

120 hours

6. List with description of all entities that may be affected by the proposed rule:

Licensed Pharmacies, Pharmacists, Manufacturers, and Distributors; Registered Pharmacy Technicians

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

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.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

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Approved for publication:



Authorized Signature

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Date Submitted

Approved for implementation:



Authorized Signature

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