

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 8

Relating to: Controlled Substances Requirements

Rule Type: Both Permanent and Emergency

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

Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

2. Detailed description of the objective of the proposed rule:

Wisconsin Administrative Code Chapter Phar 8 was recently repealed and recreated. As a result of this change, the Board has found additional areas of Phar 8 that may need to be revised to align with current Pharmacy practices and federal regulations.

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 8 includes requirements for controlled substance prescribing, record keeping, partial dispensing, and compliance with federal laws and regulations, among other requirements. The proposed rules would add to the existing requirements to address issues such as controlled substances prescribing, partial dispensing, and reporting and to create consistency between the code, current pharmacy practices and federal regulations.

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

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

450.02 (3) (a) The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

450.02 (3) (b) The Board may promulgate rules establishing security standards for pharmacies.

450.02 (3) (d) The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

961.31 The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

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

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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