

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 8

Relating to: Requirements for controlled substances

Rule Type: Permanent

This amended Statement of Scope replaces the Statement of Scope submitted to the Governor on September 26, 2018, approved by the Governor on February 22, 2019 and published as SS # 026-19 on March 11, 2019. A Preliminary Public Hearing on the Statement of Scope was requested by JCRAR on March 12, 2019. The Pharmacy Examining Board held the Preliminary Public Hearing on April 12, 2019 resulting in this revised Statement of Scope.

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 complete a comprehensive review of Phar 8, Requirements for Controlled Substances and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices.

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:

The Board intends to modernize Phar 8 to bring it in line with current pharmacy standards and practices. The Board will evaluate reducing the regulatory impact on pharmacies without negatively impacting public safety. The board will also incorporate minimum standards to prevent controlled substance diversion.

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 :

150 hours

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

Pharmacies, pharmacists, manufacturers and wholesale 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):

Minimal to moderate. It is not likely to have a significant economic impact on small businesses.

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Authorized Signature

April 16, 2019
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