STATEMENT OF SCOPE

WISCONSIN PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Sterile Pharmaceuticals and Non-Sterile Pharmaceuticals

Rule Type: Permanent

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

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

The Wisconsin Pharmacy Examining Board seeks to repeal this rule in its entirety, and to replace it with references to the United States Pharmacopeia (USP) chapters 795 (Pharmaceutical Compounding – Non-Sterile Preparations) and 797 (Pharmaceutical Compounding – Sterile Preparations).

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 seeks to repeal this rule in its entirety and replace it with references to specific USP chapters related to standards for non-sterile compounding and sterile compounding because ch. Phar 15, as it currently exists, is an outdated model for sterile pharmaceuticals. Moreover, the Board currently does not have any rules which specifically reference the standards to which non-sterile compounding must occur. In order to best protect the public, the Board seeks to provide specific references to USP standards pertaining to both sterile and non-sterile compounding. The Board concludes that the proposed rule should cover both sterile and non-sterile compounding in a concise manner that is similar to Minnesota's pharmacy rule under Minn. R. 6800.3300 (2011).

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

Section 450.02(3)(a), Stats., authorizes the Board to promulgate rules "[r]elating to the manufacture of drugs and the distribution and dispensing of prescription drugs." Moreover, s. 450.02(3)(e) authorizes the Board to promulgate rules "[e]stablishing the minimum standards for the practice of pharmacy." The "practice of pharmacy" is defined under s. 450.01(16)(b) to include the "[c]ompounding, packaging, labeling, dispensing, and the coincident distribution of drugs and devices." Under s. 450.01(3), "'[c]ompound' means to mix, combine or put together various ingredients or drugs for the purpose of dispensing."

Section 15.08(5)(b), Stats., allows each examining board to "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."

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

40 hours.

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

Pharmacies and pharmacists.

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 United States Pharmacopeia and The National Formulary (USP–NF) is a book of public pharmacopeial standards. It contains standards for chemical and biological drug substances, dosage forms, and compounded preparations. These standards have been recognized in the U.S. Federal Food, Drug and Cosmetic Act since it was first enacted in 1938. The U.S. Federal Food, Drug, and Cosmetics Act designates the USP–NF as official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the standards in USP–NF to avoid possible charges of adulteration and misbranding.

USP standards are recognized in a variety of U.S. federal legislation. The USP's drug standards are referenced throughout the provisions of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. ss. 351 – 360 (2010). As it relates to compounding, federal law requires a licensed pharmacist to comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding. 21 U.S.C. s. 353(b)(1)(A)(i)(I) (2010).

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

This rule may have a significant economic impact on small business that choose to compound or provide sterile pharmaceuticals.

Contact Person: Kris Anderson, DSPS (608) 261-2385

Gregory Blue

Department Head or Authorized Signature

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Date Submitted