# STATEMENT OF SCOPE

## PHARMACY EXAMINING BOARD

**Rule No.:** Phar 15

**Relating to:** Compounding 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 objective of the rule is to update Wisconsin Administrative Code Chapter Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797 that are effective on November 1, 2023. The Board will also be incorporating USP General Chapter 800 that has been available since December 1, 2019, as well as USP General Chapter 825, which has been available since December 1, 2020.

**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 Pharmacy Examining Board recently completed a revision to Phar 15 which became effective on August 1, 2022. The new updated USP standards for General Chapters 795 and 797 were recently released and will be effective in late 2023. Both USP General Chapters 800 and 825 also become effective on November 1, 2023.The Board would like to update Phar 15 to align with the current standards as soon as possible.

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

**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:**
Pharmacies, including pharmacies located within hospitals, 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 states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, and labeling requirements. Outsourcing facilities may also distribute compounded drugs in response to an order that is not patient specific.

The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

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

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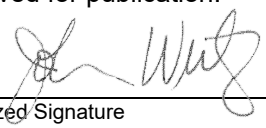
Approved for publication:



Authorized Signature

12/15/2022

Date Submitted

Approved for implementation:

Authorized Signature

2/13/2023

Date Submitted