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 review the updated United States Pharmaceopeia (USP) 797 standards, which have an intended publication date of June 1, 2019 with an anticipated official date of December 1, 2019, and amend Phar 15 to align with the USP 795 and 797 chapters without creating an unnecessary burden on Wisconsin pharmacies.

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 major revision to Phar 15 which became effective on November 1, 2018. During the legislative review period, the Pharmacy Examining Board represented to the Joint Committee on Review of Administrative Rules and stakeholder associations that when the new USP 797 chapter is published the Pharmacy Examining Board would monitor relevant USP compounding chapters and update Phar 15 so that it remains aligned with USP standards.

This proposed rule would review chapter Phar 15 with the USP compounding chapters and make necessary updates to chapter Phar 15.

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:

200 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, labeling requirements and may distribute compunded 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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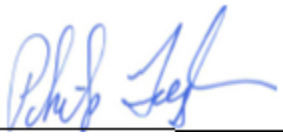

Authorized Signature

February 27, 2019

Date Submitted