

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Re-use of personal protective equipment

Rule Type: Emergency

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

On March 17, 2020, the Pharmacy Examining Board granted a variance of s. Phar 15.32 (5), pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists and compounding personnel to re-use personal protective equipment subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. The purpose of the request was to compensate for a shortage of PPE during the COVID-19 emergency. The variance was in effect for 90 days. On July 23, 2020 the Pharmacy Examining Board determined that the requirements of s. 450.02(3m)(b), Stats. have been met and extended the variance for another 90 days.

The Pharmacy Examining Board recognizes that there remains a shortage of professional personal protective equipment. The Pharmacy Examining Board determines that the preservation of the public health and safety necessitates an emergency rule to allow for compounding personnel to be able to use the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. Without an emergency rule, the ability to compound pharmaceuticals will be impacted resulting in patients not receiving their medications.

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

The objective of the rule is to allow sterile compounding personnel to re-use coveralls, shoe coverings, hair and facial hair covers, face masks, eye shields and gloves when in the pharmacist's professional judgment the condition of the equipment and suitability for re-use.

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:

Current rule states that when compounding personnel the buffer or segregated compounding area, a gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re-entering the compounding area.

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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 :

70 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 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):

Minimal or no economic impact.

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Authorized Signature

September 30, 2020
Date Submitted