

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 136-20, was approved by the Governor on October 16, 2020, published in Register 778A3 on October 19, 2020, and approved by the Pharmacy Examining Board on December 3, 2020.

This emergency rule was approved by the Governor on December 23, 2020.

ORDER

An order of the Pharmacy Examining Board to amend Phar 15.32 (5), relating to re-use of personal protective equipment.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is:

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 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 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 its suitability for re-use. Without an emergency rule, the ability to compound pharmaceuticals will be impacted resulting in patients not receiving their medications.

ANALYSIS

Statutes interpreted: None.

Statutory authority: Sections 15.08 (5) (b) and 450.02 (3) (e), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats., provides that each examining 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.

Section 450.02 (3) (e), Stats., provides the Board may promulgate rules establishing minimum standards for the practice of pharmacy.

Related statutes or rules:

Chapter Phar 7 provides standards for the practice of pharmacy.

Plain language analysis:

The emergency rule allows compounding personnel to use the pharmacist's professional judgment regarding the condition of personal protective equipment and its suitability for re-use.

Summary of, and comparison with, existing or proposed federal statutes and regulations:

None.

Comparison with rules in adjacent states:**Illinois:**

Rules of the Illinois Department of Financial and Professional Regulation specify the standards for pharmaceutical compounding (68 Ill. Adm. Code 1330.640). The standards, including standards for the re-use of personal protective equipment, are as set forth in the 2019 edition of the U.S. Pharmacopeia (USP) Compounding Compendium. On May 6, 2020, the USP added recommendations to its standards to, in response to stakeholder input, allow reuse of certain garb or personal protective equipment (*USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Low- and Medium-Risk Sterile Compounding During COVID-19 Pandemic*).

Iowa:

Rules of the Iowa Board of Pharmacy specify the standards for sterile pharmaceutical compounding (657 IAC 20.4). The standards, including standards for the re-use of personal protective equipment, are as set forth in the current revision of the U.S. Pharmacopeia (USP) Chapter 797 standards. On May 6, 2020, the USP added recommendations to its standards to, in response to stakeholder input, allow reuse of certain garb or personal protective equipment (*USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Low- and Medium-Risk Sterile Compounding During COVID-19 Pandemic*).

Michigan:

Michigan law requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services (MCL 333.17748a). The pharmacy must be accredited by the Pharmacy Compounding Accreditation Board and be in compliance with U.S. Pharmacopeia standards. On May 6, 2020, the USP added recommendations to its standards to, in response to stakeholder input, allow reuse of certain garb or personal protective equipment (*USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Low- and Medium-Risk Sterile Compounding During COVID-19 Pandemic*).

Minnesota:

Rules of the Minnesota Board of Pharmacy require pharmacies compounding sterile drug preparations to follow United States Pharmacopeia, chapter 797 standards, including standards for the re-use of personal protective equipment (Minnesota Rules, part 6800.3300). On May 6, 2020, the USP added recommendations to its standards to, in response to stakeholder input, allow reuse of certain garb or personal protective equipment (*USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Low- and Medium-Risk Sterile Compounding During COVID-19 Pandemic*).

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board recognizes that, due to the COVID-19 public health emergency, there remains a shortage of personal protective equipment. As a result, the Board has determined that preservation of public health and safety necessitates an emergency rule that allows compounding personnel to use the pharmacist's professional judgment regarding the condition of personal protective equipment and its suitability for re-use.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

As the emergency rule would allow compounding personnel to use the pharmacist's professional judgment regarding the condition of personal protective equipment and its suitability for re-use, there is no anticipated effect on small business.

Fiscal estimate:

This emergency rule will not have a fiscal impact.

Effect on small business:

The emergency rule does not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Dale Kleven, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone (608) 261-4472; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Dale Kleven, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be submitted by the date and time at which the public hearing on this emergency rule is conducted. Information as to the place, date, and time of the public hearing will be published on the Legislature's website and in the Wisconsin Administrative Register.

TEXT OF RULE

SECTION 1. Phar 15.32 (5) is amended to read:

Phar 15.32 (5) When compounding personnel exit 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 unless, in the professional judgement of the pharmacist, the items are suitable for re-use.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect upon publication in the official state newspaper, pursuant to s. 227.22 (2) (c), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chairperson
Pharmacy Examining Board