STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

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The statement of scope for this rule, SS #059-19, was approved by the Governor on July 29, 2019, published in Register 764A1 on August 5, 2019, and approved by the Pharmacy Examining Board on August 15, 2019. This emergency rule as approved by the Governor on September 19, 2019

## ORDER

An order of the Pharmacy Examining Board to create Phar 7.20 relating to automated technology product verification check.

Analysis prepared by the Department of Safety and Professional Services.

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## 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:

The Pharmacy Examining Board may authorize a pilot program and grant a waiver or variance in connection with the pilot program from any rule promulgated by the Board and the pilot program may not last longer than 3 years pursuant to s. 450.02 (3r), Stats. The pilot program waives Phar 7.01(1)(c) and (d), Wis. Admin. Code. Pharmacies have been operating in the pilot program since October 1, 2016.

Without a rule in place when the pilot program expires, pharmacies will be unable to utilize automated technology to complete the final check. This will have a negative impact on patient services.

CR 19-023 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption.

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## ANALYSIS

**Statutes interpreted:** s. 450.11, Stats.

**Statutory authority:** ss. 450.02 (2) and (3) (a), (d) and (e), Stats.

**Explanation of agency authority:**

The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05. [s. 450.02 (2), Stats.]

The board may promulgate rules:

(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

**Related statute or rule:** ch. Phar 7

**Plain language analysis:**

This rule allows for the product verification of a prescription to be completed by automated technology.

Automated technology can be utilized for the product verification of a prescription if the machine is located within the pharmacy, utilizes barcodes or other machine-readable technology and the automated technology is validated for accuracy.

Product verifications can be done by automated technology if it is contained in a final package from a manufacturer or if a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, strength, form, control or lot number and beyond use date.

The medication is required to be administered by a health care provider or a person authorized to administer drugs within an institution.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, names of supervising pharmacist, managing and supervising pharmacist responsibilities, manufacturer's recommended maintenance and quality assurance measures, dates of all software upgrades, and documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

**Summary of, and comparison with, existing or proposed federal regulation:** None

**Comparison with rules in adjacent states:**

**Illinois**: Illinois does not allow for automated technology to complete the product verification.

**Iowa**: Iowa allows automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. If the product is going to require further manipulation than a pharmacist is required to do the product verification prior to dispensing to a patient.

**Michigan**: Michigan does not allow for automated technology to complete the product verification.

**Minnesota:** Minnesota does not allow for automated technology to complete the product verification.

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

This rule was posted for economic comments and none were received. This rule does not require a pharmacy to utilize automated technology product verification process in the pharmacy.

**Fiscal Estimate:**

The Fiscal Estimate and Economic Impact Analysis is attached.

**Effect on small business**:

These proposed rules do 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**:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before October 23, 2019 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. Phar 7.20 is created to read:

**Phar 7.20 Automated technology product verification (1)** DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

**(2)** AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

**(3)** ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

**(4)** POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

**(5)** RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
4. Documentation of the dates of all software upgrades.
5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

SECTION 2. EFFECTIVE DATE. This emergency rule shall take effect upon publication in the official state newspaper.

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(END OF TEXT OF RULE)

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Dated September 25, 2019 Agency _____

Chair of the Pharmacy Examining Board