Clearinghouse Rule 19-023

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE)

PROPOSED 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.

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 to be completed by automated technology.

Automated technology (machines) 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 the licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, 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 administrater drugs at the 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.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for automated technology to complete the product verification on October 1, 2016. The purpose was to study the accuracy and determine whether allowing automated technology improves the safety, quality or efficiency of the practice of pharmacy. The Pharmacy Examining Board determined that the procedures utilized in the pilot program were sufficient for the safety of the public and is amending the rules to allow for this practice.

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

Fiscal Estimate and Economic Impact Analysis:

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, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on April 12, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.20 is created to read:

Phar 7.20 Automated technology product verification (1) DEFINITIONS. In this section product verification means doing a check of the accuracy and correctness of the drug product and label requirements.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Automated technology may perform the product verification of a prescription which meets all of the following:

(a) Located within the licensed pharmacy.

(b) Utilizes barcodes or machine readable technology to complete the product verification.

(c) The automated technology shall be 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) The automated technology shall be revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) SUPERVISING PHARMACIST RESPONSIBILITIES. A supervising pharmacist, licensed in this state, shall be identified for each technology to be accountable for the operations and outcomes of the product verification checks. The supervising pharmacist is responsible for the product verification made by the automated technology.

(4) ELIGIBLE MEDICATIONS. The automated technology may do the product verification if the medications meet all of the following:

(a) Contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.

(b) A pharmacist performs the drug utilization review under Phar 7.03

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

(5) 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.

(6) 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. Names of the supervising pharmacist including the start and end date of supervision responsibilities.
3. Documentation of managing pharmacist and supervising pharmacist of responsibilities.
4. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
5. Documentation of the dates of all software upgrades.
6. 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. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)
