STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 19-023**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The Pharmacy Examining Board began a pilot program to utilize automated technology for the product verification portion of the final check of a prescription prior to dispensing. The purpose of utilizing automated technology for product verification is to increase the availability of a pharmacist for involvement in other patient care activities. This rule creates a process for automated technology to safely complete the product verification portion of the final check of a prescription instead of a pharmacist.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on April 12, 2019. The following people either testified at the hearing, or submitted written comments:

Joel Kurzman, representing National Association of Chain Drug Stores

T**he Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:**

The National Association of Chain Drug Stores supports the rule. However, Mr. Kurzman indicated the rule should not be limited to institutional pharmacies; rather be expanded to include community pharmacy settings.

The Pharmacy Examining Board explains modifications to its rule-making proposal prompted by public comments as follows:

The Board did not make any changes based upon the public comment. The pilot program did not include community pharmacy settings, so there is no data for the Pharmacy Examining Board to evaluate the safety of utilizing this process in a community pharmacy setting where there is not the additional safeguard of the medication being administered by a healthcare professional who would recognize if there was an incorrect product.

The Pharmacy Examining Board did make some changes to the rule prompted by public hearing comments of the companion rule CR 19-023 in order to maintain consistency. Changes include clarifying the definitions of product verification; creating a definition of supervising pharmacist; replacing "strength" for "dose"; and clarifying records required to be kept.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5f: What is the difference between "product verification" as used throughout the proposed rule and automated technology "validation" as used in s. Phar 7.20 (2) (c) and (d).

Response: "Product verification" refers to ensuring the product is the correct product. "Validation" refers to the ensuring the automated technology is performing with a certain error rate.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

This rule does not have an effect on small business. The utilization of automated technology for product verification is optional.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-023)

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 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.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for automated technology to complete 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:

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 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.

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. 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)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated April 16, 2019 Agency _____

Chair of the Pharmacy Examining Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
14 March 2018

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7.20

4. Subject
Automated technology conducting product verification

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☐ No

11. Policy Problem Addressed by the Rule
This rule allows for automated technology to complete the product verficiation. The Pharmacy Examining Board initiated a pilot program on October 1, 2016 and has determined that the procedures utilized in the pilot program were sufficient for the safety of the public and increases the availability of a pharmacist for involvement in other patient care activities.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the State's Economy as a Whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit of the implementing this rule is to allow for the pharmacist to be involved in other patient care activitites.

16. Long Range Implications of Implementing the Rule
The long range implication is automated technology will complete product verifications and pharmacists will be able to focus on other patient care activities.

17. Compare With Approaches Being Used by Federal Government
None

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Iowa allows for 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. Illinois, Michigan and Minnesota do not allow for automated technology to compete the product verification.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No