STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 19-024**

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 delegate-check-delegate for the product verification portion of the final check of a prescription prior to dispensing. Delegate-check-delegate allows a person delegated by the pharmacist to check the product verification of a product prepared by another person delegated by the pharmacist. The purpose of utilizing delegate-check-delegate for product verification is to increase the availability of a pharmacist for involvement in other patient care activities. This rule creates a process for delegate-check-delegate 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:

Erica Martin, representing Pharmacy Society of Wisconsin
Joel Kurzman, representing National Association of Chain Drug Stores
Philip Brummond representing Froedtert and Medical College of Wisconsin
Tomson George, representing Walgreens
Michelle Farrell, representing Boscobel Pharmacy
Noah Franz
Eric Gresens
Amr Elsayed

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

Everyone who testified is in support of the proposed rule. Ms. Farrell indicated during the pilot program, her pharmacy had a 26% increase in pharmacist interventions with patients, including comprehensive medication reviews, CPAP machine rentals and diabetic footwear fittings, allowing the pharmacy to better serve the community's health needs. Froedtert Hospital conducted a study that showed they were able to provide the same level of patient safety while decreasing pharmacy processing time, developing their technician workforce and reallocating pharmacist staff from distributive roles in central pharmacy to decentralized clinical activities. Without this proposed rule, Froedtert Hospital's patient care services would be negatively impacted. Froedtert Hospital and Medical College of Wisconsin expanded the practice model to their community pharmacies and pharmacists were able to spend more time providing direct patient care while maintaining their high quality medication dispensing process. Mr. Gresens indicates the pilot program allowed the pharmacist time to provide clinical duties and the technicians showed a high level of accuracy.

Mr. Elsayed requested more detail in the rule as to how the quarterly accuracy checks should be implemented.

Mr. Franz requested the removal of documenting the type of errors which occur.

Pharmacy Society of Wisconsin supports the proposed rule and requested the consideration of the following modifications:

- Eliminate the requirement for artificial errors to be introduced.
- Eliminate the requirement for a description of the medication on the prescription label to allow a non pharmacist to check the accuracy of the medication.
- Eliminate the recording of the type of error which occurs.
- Eliminate references to the supervising pharmacist, which is not defined; instead refer to managing pharmacist.
- Eliminate the requirement to record the control or lot number on repackaging.
- Add a definition of "delegate-check-delegate."
- The delegate-check-delegate process should only include production verification and not label verification.
- Change "dose" to "strength" for consistency.
- Include in the 4-state analysis that Minnesota allows for delegates to complete the final product through variances since 1989 and Michigan allows delegate-check-delegate in inpatient settings.

National Association of Chain Drug Stores supports the proposed rule and requested the consideration of the following modifications:

- Allow for alternative training to implement technology assisted verification systems.

- Allow delegates to perform product verification on prescriptions they filled themselves utilizing barcodes.
- Eliminate the requirement that a delegate achieve an accuracy rate of at least 99.8%.
- Clarify the eligible medications.
- Change "dose" to "strength".
- Allow for quality assurance process to be done by existing Continuing Quality Improvement programs.
- Grandfather delegates already validated in the pilot programs.

Walgreens supports the proposed rule and requested the consideration of the following modifications:

- Allow delegates to perform product verification on prescriptions they filled themselves utilizing barcodes.
- Eliminate the requirement that a delegate achieve an accuracy rate of at least 99.8%.
- Eliminate the requirement for artificial errors be introduced. A safer alternative would be to include simulated errors in the training program.
- Allow for any product to be verified by a delegate if the prescription was filled using barcode scanning.
- Allow for quality assurance process to be done by existing Continuing Quality Improvement programs.

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

The Pharmacy Examining Board made the following modifications:

- Replaced the requirement to artificially introduce errors in the validation process to simulating errors during the training process.
- Created definitions for "delegate-check-delegate" and "supervising pharmacist".
- Modification to the lot or control number.
- Removed label verification from the delegate-check-delegate process.
- Replaced "dose" to "strength" throughout the rule.
- Clarified the eligible product section.
- Created a provision for delegates validated during the pilot program to meet the qualifications under the proposed rule.

The Pharmacy Examining Board considered but did not make modifications on the following:

- The requirement for a description of the medication on the prescription label is necessary in the community setting so that the patient or patient's agent may determine if there is an error prior to taking the medication. This requirement is not necessary in the institutional 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 pilot program did not include a delegate conducting product verification as part of the final check of their own product preparation, so there is no data for the Pharmacy Examining Board to evaluate the safety.
- The requirement that a delegate achieve an accuracy rate of at least 99.8% is required to ensure the public's safety.
- The quality assurance provisions are minimal standards and can be incorporated into an existing continuing quality improvement program.
- Minnesota creates variances from the rules to allow for delegate-check-delegate. A review of Michigan rules did not reveal any provisions relating to delegate-check-delegate.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5b: In s. Phar 7.21 (2) (b), it appears that the word "pharmacy" should be inserted before the phrase "technician training program", and the word "pharmaceutical" should be inserted before the phrase "product selection".

Response: The word "pharmaceutical" is not inserted because there are products which may not be considered pharmaceutical.

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 delegate-check-delegate 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 19-024)

PROPOSED ORDER

An order of the Pharmacy Examining Board to create Phar 7.21 relating to delegate check delegate.

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, 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 delegate-check-delegate.

Delegate-check-delegate allows a person delegated by the pharmacist to check the product verification of a product prepared by another person delegated by the pharmacist.

In order for a person to be delegated product verification, the individual must meet all of the following: be 18 years of age; completed an accredited technician training program or has a minimum of 500 hours of experience in product selection labeling and packaging; completed a didactic and practical training curriculum; and completed a validation process.

The didactic and practical training curriculum must include elements of a package label; medication and pharmacy abbreviations needed to match ordered medication with dispensed medication; common dispensing medication errors and concepts; eligible medications; policies and procedures on reporting of medication errors; overview of the pharmacy's medication use process and a practical training designed to assess the competency of the individual. The validation process requires a check of 500 product verifications over at least 5 days with an accuracy rate of at least 99.8%.

A product is eligible in institution pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In an institutional pharmacy the medication is required to be administered by a health care provider or a person authorized to administration drugs at the institution.

Product verifications can be done by delegates in community pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In a community pharmacy the medication is required to include a description of the medication on the prescription label that allows for a patient to check the accuracy of the medication.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, documentation of supervising and managing pharmacist responsibilities and dates of supervision responsibilities.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding technician-check-technician.

Iowa: Iowa has rules regarding technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and trained in technician-check-technician (including medication errors). There shall be a supervising pharmacist. The pharmacy is required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration.

Michigan: Michigan does not have rules regarding technician-check-technician.

Minnesota: Minnesota does not have rules regarding technician-check-technician.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate-check-delegate on October 1, 2016. The purpose was to study the accuracy and determine whether delegate-check-delegate 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.

The Pharmacy Examining Board also received information from the Pharmacy Society of Wisconsin's community delegate-check-delegate study.

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 delegate-check-delegate 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 7.21 is created to read:

Phar 7.21 Delegate-check-delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

(b) "Delegate-check-delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

(c) "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.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

(b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
    a. Drug name.
    b. Strength.
    c. Formulation.
    d. Expiration date.
    e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong strength.
    c. Wrong formulation.
    d. Extra or insufficient quantity.
    e. Omitted medications if utilizing unit dose or compliance packaging.
    f. Expired medication.
    g. Look-alike or sound-alike errors.
    h. High-alert medications.
3. Eligible medications for delegate-check-delegate.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
    a. Procurement.
    b. Ordering.
    c. Dispensing.
    d. Administration.
    e. Monitoring.
6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
    a. Wrong drug.
    b. Wrong strength.
    c. Wrong formulation.
    d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

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

(e) Notwithstanding, par (a) to (d), a delegate who completed the pilot program validation process between October 1, 2016 and September 30, 2019 meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4)

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if the medications meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Includes a description of the medication on the prescription label that allows for a non pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

1. Name of the product verification delegate.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.
6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate 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 delegate 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 accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.
3. Quality assurance audits and quarterly assessments.

(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
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

2. Date
14 March 2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7.21

4. Subject
Delegate check delegate

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 a delegate 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 delegates may 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)
Iowa allows for technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and trained in technician-check-technician (including medication errors).

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

There shall be a supervising pharmacist. The pharmacy is required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration. Illinois, Michigan and Minnesota do not allow for technician-check-technician.

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.

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

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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