

Report From Agency

**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.