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 19-023**

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.