

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 23-031**

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 object of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 25. This was accomplished by creating chapter Phar 18, entitled Third-Party Logistics providers, a new chapter in the Wisconsin Administrative Code that outlines requirements for a new optional state license.

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 August 31, 2023. The following people either testified at the hearing, or submitted written comments:

- Kristine Burrows, State License Servicing, Inc.

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

- Ms. Burrows asked that the Board make it clear whether a Third-Party Logistics may choose not to obtain a license. She pointed out that the language differs from what is outlined for Wholesale Distributors.

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

- Modifications were made to the Plain Language Analysis, Phar 18.01, 18.03 (3), 18.04, and 18.08 to clarify the optional nature of the license.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: 6. In the agency's plain language analysis, it indicates the federal rules have not yet been finalized. Does the agency intend to update s. Phar 18.08 to specifically identify the federal regulations for which compliance is required under state licensure? Similarly, can the agency more specifically identify which state laws and regulations must be complied with in order to avoid disciplinary action under s. Phar 18.08? At this point in the rulemaking process, can the agency confirm that the substantive requirements of the proposed rule, such as those in ss. Phar 18.06 and 18.07, are no more strict than requirements under federal law, as required by s. 450.075 (4), Stats.

Response: The Pharmacy Examining Board accepts this comment and responds to the questions posed as follows: The Board can confirm that the requirements in Phar 18 are not more strict than 21 USC 360eee as required by s. 450.075 (4), Stats. The Board expects licensees to continue to follow the requirements set out in the Drug Supply Chain Security Act, regardless of whether those requirements change in the future for Third-Party Logistics providers. Any future changes to the Drug Supply Chain Security Act would take precedence over the optional state license. The Board would also like to note that similar compliance language is being utilized without issue in Phar 12.05 and 13.17.

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: N/A