

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 19-165**

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:

Currently the professional service area is required to have a refrigerator, sufficient shelf, drawer or cabinet space for labels and containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment. As health care evolves, there are different types of pharmacies, specifically consulting pharmacies, which may not require all the items listed in the current rule. The proposed rule will update the rule to reflect the requirements for current practices of pharmacy.

The rule also clarifies the manner in which controlled substances must be stored.

In addition, the rule clarifies the provisions relating to temperature and humidity due to stakeholder concerns raised following the implementation of CR 16-073.

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 January 30, 2020. No one testified at the hearing or submitted written comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5a: Consider revising Section 3 of the rule text for clarity. The term "diversion" may refer to a range of activities in medical and legal contexts. The board could consider including a definition for the term or adding language to clarify the

intended use. Also, because “theft” is considered a type of diversion in most cases, the use of the phrase “theft or diversion” may lead to confusion. The board should consider changing the standard to “a manner that obstruct theft or other diversion of the controlled substance from its legitimate and intended medical purpose.”

Response 5a: The Pharmacy Examining Board rejects this comment because the language in the proposed rule is consistent with the federal language regarding the storage of controlled substances. The Pharmacy Examining Board does not want to have different language which may inadvertently create confusion between the federal and state rules.

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 economic impact on small businesses.