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 24-092**

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 recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmacopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

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 February 20, 2025 on CR 24-092. The following people either testified at the hearing, or submitted written comments:

- Danielle Womack, Vice President of Public Policy and Advocacy for the Pharmacy Society of Wisconsin

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

- The Pharmacy Society of Wisconsin submitted the following comments:
  - Is it the Board's intent to require compliance with USP General Chapter 800, whether they compound or not?
  - Can a pharmacy document a different timeframe or do 14-day beyond-use dates for flavoring under Phar 15.02 (1)(b) required?
  - What patient protection is offered if flavoring is not considered compounding?

- What grounds does the Board have for disciplinary action for failure to meet "should" standards under USP General Chapter 797?
- Does USP General Chapter 797 being incorporated by reference into the Administrative Code mean that compliance is required with all other USP chapters cited in that chapter?
- Will copies of the incorporated chapters be available through the Legislative Reference Bureau?
- How should pharmacies label non-patient-specific or office use compounding products?

The Pharmacy Examining Board made the following modifications to its rule-making proposal based on public comments:

- Phar 15.02 (1) (b) is revised to read "the pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless a shorter beyond-use-date has been documented."
- The following has been added to section Phar 15.03: "**(2)** DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

  (b) Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

  (c) Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern."

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2b: "Should the material created in s. Phar 15.03 either be moved to, or at least referenced within, current s. Phar 10.03? Additionally, it is confusing that the provisions says it only "may" be considered a violation. Does that give adequate notice to practitioners about what is required?"

Response: The board accepts this comment and would like to note that the standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need to give notice to licensees.

Comment 2c: "The agency could consider whether an initial applicability clause should be added to the proposed rule, if there could be circumstances in which the new rule could apply to compounding that was initiated before the effective date of the rule. [s. 1.06 (3), Manual.]"

Response: The board accepts this comment and would like to note that standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need an initial applicability clause.

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