Report From Agency

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	**:**	**REPORT TO THE LEGISLATURE CR 22-007**

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 objective of the rule is to review the updated United States Pharmacopeia (USP) 795 and 797 standards, which originally had a publication date of June 1, 2019 with an anticipated official date of December 1, 2019. However, due to appeals filed, the 2019 revisions of the USP are currently on hold. The 2008 USP 795 and 797 are the current standard for pharmacy compounding until those 2019 standards are published and effective.

Even though the Board will not be moving forward with the 2019 revisions at this time, there are still updates that need to be made to Phar 15 to align it with the 2008 USP 795 and 797 chapters that are currently in effect. It is the Board's intent to amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current USP chapters. When new updated standards are available, the Board will consider opening a new scope statement to address any further changes if applicable.

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 14, 2022. The following people either testified at the hearing, or submitted written comments:

- Richard L. Green, BS Pharm, R.Ph., BCNP, FAPhA, Director of Radiopharmacy Practice, Cardinal Health Nuclear & Precision Health Solutions
- John Long, R.Ph., MBA, Director Regulatory Affairs, CVS Health

- Danielle Womack, Vice President of Public Affairs, Pharmacy Society of Wisconsin
- Brian L. Koenig, PE, MBA, CNBT, Technical Safety Services

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

- Cardinal Health Nuclear & Precision Health Solutions provided a summary of the practice of nuclear pharmacy in Wisconsin. They also highlighted the recent addition of USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, which outlines nuclear pharmacy standards for compounding previously covered in USP General Chapter <797>. Finally, they encouraged the Board to write regulations requiring that Wisconsin nuclear pharmacists follow USP General Chapter <825>.
- CVS Health provided comments that there is confusion over the objective of the rule change, as well as the mix of terminology between the currently effective 2008 USP General Chapter <797>, the 2019 version that was never published, and the recently released version from 2021. They therefore requested further clarification on the rule.
- The Pharmacy Society of Wisconsin made two recommendations. The first, was a request for the Board to be consistent throughout the rule with its use of terms such as "stored in a refrigerator" or "stored in a freezer" versus providing specific temperatures for refrigerated or frozen products. The second recommendation was that the Board consider using the term "products" instead of "packages" in Phar 15.34 to align with the proposed revisions of the USP General Chapter <797>.
- Brian Koenig provided comments requesting clarification from the Board on whether they intend to add to the current Phar 15 or adopt the future version of USP General Chapter <797> instead. Mr. Koenig also recommended that the Board consider adopting USP General Chapter <797> and then add additional statements that the Board feels are necessary.

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

- Phar 15.30 (11), (13), and (17) amended to include equivalent Celsius temperature ranges
- Phar 15.37 (5), (6), and (7) Celsius temperature ranges updated to "Controlled room temperature", "freezer", or "refrigerator" to be consistent with use of these terms in other rule sections
- Phar 15.34 updated the term "packages" to "products" to be consistent with USP language

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report have been accepted in whole. After consideration of all of the recommendations, the Pharmacy Examining Board notes here that the language laid out in Phar 15.34 for Immediate-use compounded sterile preparations is, in their opinion, necessary to clarify the requirements for this specific type of compounding.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

A report from the Small Business Regulatory Review Board was requested on December 16, 2021. No report has been received.