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 21-071**

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:

This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

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 October 20, 2021. The following people either testified at the hearing, or submitted written comments:

- Michael DeBisschop, Phm.D.
- John Long, R.Ph., MBA, Director Regulatory Affairs, CVS Health
- Danielle Womack, Vice President of Public Affairs, Pharmacy Society of Wisconsin
- Dawn Wypiszynski, Phm.D., Pharmacy Director, Morton LTC

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

- Michael DeBisschop, Phm.D.

    - Phar 8 should be updated to allow partial refills of all types of controlled substances, including repeated partial refills of schedule II prescriptions
- John Long, R.Ph., MBA, Director of Regulatory Affairs, CVS Health
    - Most of the language in current Phar 8.11 on emergency kits for long-term care facilities should be added back in
    - Add in Phar 8.01 (4) "Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law."
    - Add in language to Phar 8.05 on "quarterly reconciliation of targeted schedule III-IV controlled substances"
    - Add in Phar 8.06 (2)(d) "The drug is delivered to the patient's home, or any address as requested by the patient, through mail, common carrier or delivery service."
- Danielle Womack, Vice President of Public Affairs, Pharmacy Society of Wisconsin
    - Phar 8.05 wording should be clarified that two years for pseudoephedrine recordkeeping is enough per statute
    - Phar 8.05 should include a definition for "perpetual inventory"
    - Phar 8.07 (2) should include language for electronic prescriptions accepted within 7 days of an emergency fill
    - Language in current Phar 8.11 on emergency kits for long-term care facilities should be added back in
    - Phar 8 should allow for partial dispensing of controlled substances
    - Phar 8 should include the definition for "valid signature" for controlled substance prescription orders
- Dawn Wypiszynski, Phm.D., Pharmacy Director, Morton LTC
    - Clarification requested in Phar 8.01 (3) (Note) on whether this note is enforceable law.
    - Clarification requested in Phar 8.03 (1) on "what defines what a pharmacist 'reasonably should know'?"
    - Clarification requested in Phar 8.03 (2) on whether this language is separating a prescription from a medication order for practitioner general dispensing
    - Phar 8.04 should include contact information for the Board and proper method for this notification should be provided.
    - Clarification requested in Phar 8.05 on monthly inspections
    - Phar 8.07 (2) should include contact information for the Board and proper method for this notification should be provided.
    - Phar 6.04 (3) (a) 4 is missing from the Wisconsin Administrative Code
    - Phar 8 should include a definition for "valid signature" for controlled substance prescription orders
    - Clarification of the definition of "practitioner's agent" from current Phar 8.12 (1) and 2 (b) (c)
    - Clarification requested on the requirements for an original hard copy prescription from current Phar 8.12 (3)

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

- Phar 8.01 (4) added as recommended by public comment
- Phar 8.05 updated to include only statutory requirements for recordkeeping and quarterly controlled substance inspection requirements.
- Phar 8.06 (2) added to include an exemption to the identification card requirement for prescription delivery
- Phar 8.07 changed from dispensing controlled substances in emergency situations to partial dispensing requirements
- Phar 8.08 changed from dispensing and sale of pseudoephedrine products to controlled substances in emergency kits for long term facilities requirements

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report have been accepted in whole. However, the Pharmacy Examining Board would like to note here that the definition language in Phar 806 (1) was kept in the rule due to the inclusion of a hospice facility under s. 50.90 (1) (c), Stats. which is not otherwise accounted for under the definition of "health care facility" in s. 450.11 (1b) (e) 3.

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