

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 23-054

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 proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101. These changes include the creation of s. Phar 6.025, which are rules that specifically apply to remote dispensing sites, as well as amendments to s. Phar 7.43 to allow for remote dispensing sites to operate without the presence of a pharmacist. Clarification was also added to ss. Phar 5.01 (4) and 8.01 (5) that pharmacies shall include remote dispensing sites. The Board also added a definition of pharmacy graduates to chapter Phar 1, and modified requirements in chapter Phar 7 to allow them to practice pharmacy while waiting for their license to be granted.

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 26, 2023. The following people either testified at the hearing, or submitted written comments:

- Richelle Andrae, Government Relations Specialist, Wisconsin Primary Health Care Association (WCHA)
- Xin Rippel, Director of Pharmacy, Family Health Center Pharmacy – Marshfield
- Michael DeBisschop, Pharm.D.
- Danielle Womack, Vice President – Public Affairs, Pharmacy Society of Wisconsin (PSW)

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

- The WCHA expressed their support of the proposed rule project and requested expedited implementation be prioritized by the Board. The WCHA also requested that the Board address an issue with labelling prescriptions from remote

- dispensing sites. Specifically, whether a separate label is allowed with the remote dispensing site's location listed.
- Xin Rippel provided background information on Family Health Center of Marshfield as it relates to pharmacy services to a rural population. They also requested clarification on the process for registering as a remote dispensing site and how that works with licensure, DEA registration and other regulatory requirements.
 - Michael DeBisschop provided suggestions for changes in the following areas of the rule project:
 - Pharmacy graduates should also be included in s. Phar 7.61.
 - Clarify whether pharmacists who supervise a remote dispensing site also have to be located at a pharmacy or if they can be supervising a remote dispensing site from a non-pharmacy location.
 - In s. Phar 7.43 (7) (c), clarify whether the 1500 hour work requirement includes internship or rotation time, or if it only applies to paid work time. Also, clarify the term "pharmacist delegate" with a definition or replace it with a more descriptive term.
 - The PSW provided suggestions for changes to ss. Phar 7.43 (6) (a) and (b). They recommended removing the term "supervising pharmacy," as the term does not accurately describe what is happening with remote dispensing sites.

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

- Phar 7.43 (4) (b) was amended to read "remote dispensing may not occur if a pharmacist is not available remotely. A pharmacist shall provide direct supervision of pharmacist delegates at remote dispensing pharmacies. A pharmacist shall be available to the pharmacist delegate either in person or contact by telecommunication means."
- Phar 7.43 (4) (a) 2. (intro.) was amended to read: "This remote dispensing location is being supervised by a pharmacist employed by:"
- Phar 7.43 (6) (intro.) was amended to read: "RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacist shall do all of the following:"
- Phar 7.43 (b) (b) was repealed.
- Phar 7.43 (7) (d) was created to read: "A pharmacist shall provide direct supervision of pharmacist delegates. A pharmacist shall be available to the pharmacist delegate either in person or contact via telecommunication means."
- Phar 7.60 and 7.61 were repealed.
- Phar 1.02 (3m) was created to read: "'Direct Supervision' means immediate, whether in person or real time video conferencing where all parties can communicate by simultaneous means of audio, video, or data communications, availability to continually coordinate, direct and inspect in real time the practice of another."

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: 5c. In s. Phar 6.025 (intro.), consider revising the introductory statements to use the active voice. [s. 1.05 (1) (d), Manual] Also, consider revising the first sentence of the introduction, is it intended that any time a pharmacist remotely supervises a location, that it is a sufficient condition to apply the specific rules for remote dispensing?

Response:The Board has accepted this comment and would like to note that any time a pharmacist remotely supervises a location, the rules for remote dispensing apply.

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