

## Pharmacy Examining Board 12/1/2022 Additional Materials Item D. Public Hearing on EmR 2213 for Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing

**DATE:** December 1, 2022

**TO:** John Weitekamp, Chairman

Members, Pharmacy Examining Board (PEB)

**FROM:** Danielle Womack, Vice President of Public Affairs

**Pharmacy Society of Wisconsin** 

**SUBJECT:** EmR 2213: Remote Dispensing

On behalf of the Pharmacy Society of Wisconsin's more than 4,000 members, I would like to thank you for the opportunity to share our thoughts on Emergency Rule 2213, relating to remote dispensing.

The Pharmacy Society of Wisconsin is dedicated to advancing pharmacy practice with the ultimate purpose of enhancing patients' lives. Therefore, we appreciate the Pharmacy Examining Board's work in updating regulations on remote dispensing to address contemporary pharmacy practice models.

Upon reviewing the preliminary rule draft, we respectfully suggest some changes based upon feedback from our membership. These changes will bring more clarity to the chapter for pharmacies while ensuring that pharmacy practice is completed safely and effectively for optimum patient safety. Below are the changes that PSW respectfully and specifically requests.

- **Phar 7.43 (3):** This section of current law states "No person may use or display the title "pharmacy", "drugstore," "apothecary," or any other title, symbol or insignia having the same or similar meanings in connection with remote dispensing." Because remote dispensing sites will now be licensed as pharmacies, we request that they be able to utilize the word "pharmacy" in their title.
- Phar 7.43 (6)(a) and (6)(b): These sections refer to a supervising pharmacy; there is no longer a requirement that a supervising pharmacy be associated with a remote dispensing site; rather, a remote dispensing site pharmacy must have a supervising pharmacist. We request that the language be changed from pharmacy to pharmacist for clarity.

To reiterate, our goal, like that of the PEB, is to advance pharmacy practice while ensuring patient safety, and we appreciate the PEB's diligence and work in implementing regulations regarding remote dispensing site pharmacies. Thank you again for allowing me to submit comments on behalf of more than 4,000 Pharmacy Society of Wisconsin members.

From: Richelle Andrae
To: DSPS Admin Rules

**Subject:** EmR2213 Public Comment - PEB

**Date:** Wednesday, November 30, 2022 4:31:29 PM

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Good afternoon.

This email is in regard to the following: **Pharmacy Examining Board (Phar 1, 5, 6, 7, 8).** EmR2213. Remote dispensing.

Thank you to the PEB for your service and for considering comments on this emergency rule. The Wisconsin Primary Health Care Association (WPHCA) is the member association for Wisconsin's 19 Community Health Centers, also known as Federally Qualified Health Centers, and Look Alike clinics. Most Community Health Centers operate pharmacies; several also currently manage remote dispensing and/or are interested in doing so in the future. WPHCA is generally supportive of the rule, and offers the following questions as points of clarification we hope will be addressed through rulemaking and/or supporting documentation:

- 1. **Pharm 6.025** It states a pharmacy "may be subject" to rules.... In practice, does that mean "shall be"? If not, under what conditions will a pharmacy be subject to the rules that are described? The word "may" is confusing here.
- 2. **Pharm 6.025** How are "Pharmaceutical services" defined for the purposes of this provision? Needs clarity. Is this restricted to just dispensing? What about administering? Other services?
- 3. Pharm 7.43 (4) (b) "...pharmacist is not available remotely..." What if a pharmacist is available in person at the RDS, then can dispensing occur? For example, what if the only pharmacist is on site at the RDS, say due to weather etc, where only one pharmacist could get to a site and it is an RDS. Suggest changing to in-person or remote options.
- 4. **Pharm 7.43 (5)(b)** "the address of the remote site on the label" Some technical labeling systems do not permit this. If the pharmacy made this change and made each site separate, they would not have the other location's information readily

available. One option would be a label attached separately with the required information.

5. **Pharm 7.43 (6)(a) 5.** What specific documentation is required for this?

Thank you,



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November 30, 2022

Nilajah Hardin, Administrative Rules Coordinator Department of Safety and Professional Services Division of Policy Development P.O. Box 8366 Madison, WI 53708-8366

Cc via email: DSPSAdminRules@wisconsin.gov; brad.wojciechowski@wisconsin.gov

Re: EMR 2213, Emergency Rule amending Pharm 1, 5, 6,7 and 8 Relating to Remote Dispensing

Dear Ms. Hardin:

We at TelePharm thank the Wisconsin Department of Safety and Professional Services (DSPS) for the opportunity to comment regarding the Wisconsin Pharmacy Examining Board's (Board) emergency rule relating to remote dispensing.

The Board has done a remarkable job ensuring Emergency Rule (EmR) 2213 aligns with the legislative directives as outlined in 2021 Wisconsin Act 101, and we applaud DSPS' request for engagement from stakeholders. While the emergency rule will enable remote dispensing from licensed pharmacy locations, linking more patients to pharmacy services than before, we recommend a few minor revisions to further this endeavor.

## Phar 7.43(3) Remote Dispensing

- This section prevents facilities which engage in remote dispensing from using or displaying the terms "pharmacy", "drugstore," "apothecary," or any other title, symbol or insignia having the same meanings.
- Statutory authority for EmR 2213 and other sections of the rule require remote dispensing sites to be licensed as pharmacies.
  - The preamble to 2021 Wisconsin Act 101 states the Act relates to the licensing and regulation of pharmacies and remote dispensing sites under pharmacy practice law and defines remote dispensing site as a "pharmacy" in section 450.01(21c) Wisconsin Statutes.
  - Phar 5.01(4) further clarifies that pharmacies shall include remote dispensing sites pursuant to s. 450.09(1)(a).
- Section 450.06(1) Wisconsin Statutes was amended to allow the word pharmacy, or similar terminology to be used to describe any place of practice licensed as a pharmacy by the board. Phar 7.43(3) was not similarly updated in EmR 2213 and prevents these locations from using such terminology to describe their practice.

• To provide clarity and ensure pharmacy regulations align with the statutory changes from 2021 Wisconsin Act 101, we recommend repealing Phar 7.43 (3) to prevent confusion for patients and licensees.

Phar 6.025 Licenses; remote dispensing sites

 This section establishes licensure requirements for remote dispensing sites and states:

A pharmacy may be subject to rules that apply only to remote dispensing sites if no pharmaceutical services is provided at that pharmacy by a pharmacist who is present in the pharmacy, and the following conditions have been met:

(1)-(4)

- A pharmacist may be on-site at a remote dispensing site and provide clinical or other pharmaceutical services outside of the mandatory once-monthly inspection frequency. These visits may be pre-scheduled or unplanned and can impact staffing, operational hours and services offered.
  - In its current form, it is unclear if Phar 6.025 requires the pharmacy to comply with the requirements for a remote dispensing site (such as the additional training for delegates) during any period the pharmacist may be present and <u>providing</u> pharmaceutical services.
- To provide clarity and ensure remote dispensing sites serving Wisconsin patients provide safe pharmacy care in compliance with statute and Board rule, we recommend the following revision:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules that apply only to remote dispensing sites if a pharmacist remotely supervises the location but is not present at that pharmacy, or a pharmacist is present and not providing no-pharmaceutical services is provided at that pharmacy. by a pharmacist who is present in the pharmacy, and the following conditions shall also have been met:

Thank you for your time and consideration and we look forward to further collaboration with DSPS and the Board regarding the permanent promulgation of rules for remote dispensing. I can be reached at jessica.adams01@telepharm.com or on my cell at (512)426-6868 for any questions.

Sincerely,

Jessica Adams, PharmD

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Director of Regulatory Affairs, TelePharm