

Report From Agency

**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 09-099
PHARMACY EXAMINING BOARD : (s. 227.19 (3), Stats.)**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

The department estimates that this rule will require staff time in the Division of Board Services. The total on-going salary and fringe costs are estimated at \$7,100. The department finds that this rule has no significant fiscal effect on the private sector.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

With the enactment of 2007 Wisconsin Act 202, the Pharmacy Examining Board created rules relating to remote dispensing sites. This proposed rule-making order sets forth the process and procedures for establishing and operating remote dispensing sites.

The Pharmacy Examining Board created a committee to draft remote dispensing guidelines after 2007 Wisconsin Act 202 became effective. The committee met once and devised several safeguards to protect the safety of the public. Since the remote dispensing model departs from the traditional dispensing model, the board sought to address drug security, and the supervision of remote site staff, privacy, labeling and quality assurance in the context of remote site dispensing. The final guidelines are the result of committee discussions and recommendations that were finalized by the full board.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on December 2, 2009.

Eric Knox, WI Department of Corrections, Waupun, WI, appeared for information only.

The following individuals appeared and provided testimony:

Matthew Mabie, Hometown Pharmacy, Cottage Grove, WI

Ted Grabarczyk, Pharm.D. Candidate, Madison, WI (also submitted written comments)

Jason Knox, Community Memorial Hospital, Oconto, WI

Tom Engels, Pharmacy Society of Wisconsin, Madison, WI (also submitted written comments)

Gary Plank, Marshfield Clinic, Stratford, WI

Summary of Public Hearing Comments:

Matthew Mabie. Mr. Mabie stated he was in support of the proposed rule, but advocated that a mileage requirement defining the geographical distance requirement should be included in the rule. He suggested a 10 mile distance requirement.

Jason Knox. Mr. Knox stated his support of the proposed rule, but did not support s. Phar 7.095 (7) (c), the 2000 hour work requirement. He argued that 2000 hours of work is not a good gauge of competency of a pharmacy technician and that evaluating a pharmacy technician's competence should be left within the supervising pharmacist's discretion. Mr. Knox suggested a training program in lieu of the 2000 hour work requirement due to the hours themselves being an inappropriate assessment tool. He suggested that the board provide more guidance on what should be included in a training program.

Tom Engels. Mr. Engels stated that he supported the proposed rules, but argued that the proposed rule should be amended to include a 10-15 mile geographical distance requirement that the board could waive by variance.

Gary Plank. Mr. Plank stated that he was in favor of the proposed rule, but did not support s. Phar 7.095 (7) (c), the 2000 hour work requirement. He stated that 2000 hours is not a good number to determine the competency of a pharmacy technician. He urged the board to strike this provision from the rule or amend the language. Secondly, Mr. Plank opposed the addition of any language defining the geographical distance requirement of remote dispensing sites with mileage requirements.

Ted Grabarczyk. Mr. Grabarczyk stated that he was opposed to the proposed rule as drafted, but that he was in support of the rule if it were amended to include a mileage requirement. He presented written comments along with a survey that he had conducted as part of his rotation with the Hometown Pharmacies (MD Group LLC).

Board's Response to the Public Hearing Comments:

After review and discussion of the comments provided at the public hearing, the board made the following changes to the proposed rules:

The board amended s. Phar 7.095 (7) (c) – the definition of “remote dispensing site.” The board deleted the language indicating that remote does not mean geographical distance and added that remote means geographical distance greater than 10 miles from an existing licensed pharmacy in Wisconsin open to the public. A modification to the distance requirement may be submitted for further board determination.

Also, the board amended s. Phar 7.095 (7) (c), amending the 2000 hour work requirement to 1500 hours. The board also changed the language relating to the training program to relevant equivalent practice.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5.b. Section Phar 7.095 (5) (a) provides that a remote dispensing site must comply with the requirements of s. Phar 7.01, including “visual access of prescription orders, labels, and dispensed product.” If the rule requires a site to comply with the requirements of s. Phar 7.01, why is special emphasis placed on prescription orders, labels, and dispensed products? It seems that a cross-reference to s. Phar 7.01 is sufficient.

Response: The board changed “Comply with the requirements under s. Phar 7.01, including visual access of prescription orders, labels and dispensed product.” To comply with the requirements under s. Phar 7.01, and visually inspect prescription orders, labels and dispensed product.”

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1), Stats.