

WISCONSIN LEGISLATIVE COUNCIL STAFF



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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 98-187

AN ORDER to create Phar 7.10, relating to pharmacists administering by injection a drug product or device in the course of teaching a patient self-administration techniques.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

11-16-98 RECEIVED BY LEGISLATIVE COUNCIL.
12-11-98 REPORT SENT TO AGENCY.

RS:PS:jal;kjf

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES NO

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CLEARINGHOUSE RULE 98-187

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]

4. Adequacy of References to Related Statutes, Rules and Forms

In the second paragraph of the analysis to this rule, the first bracketed statutory citation should be changed to read s. 15.407 (6), Stats., as that is the statute that created the Pharmacist Advisory Council. The reference to s. 450.025 is more appropriately placed at the end of the paragraph, along with s. 450.02 (2g) (b), as those two provisions relate, respectively, to the requirements placed on the council and the Pharmacy Examining Board relating to administrative rules.

5. Clarity, Grammar, Punctuation and Use of Plain Language

- a. In the fourth paragraph of the analysis, the last sentence is awkwardly worded and could be rewritten as follows: "These requirements are modeled after requirements in s. 450.035 (2), Stats., for pharmacists administering vaccines."
- b. In the fifth paragraph of the analysis, the notation "sec." on line 4 should be changed to "s."
- c. In the sixth paragraph of the analysis, the word "patient" on line 4 should be plural.
- d. The inclusion of definitions for the term "drug product" and "device" should be considered. As an alternative, s. Phar 7.10 (intro.) should include appropriate references to the

definition of "drug product" in s. 450.01 (11), Stats., and the definition of "device" in s. 450.01 (6), Stats. Also, in s. Phar 7.10 (intro.), a comma should be inserted after the word "techniques."

e. Section Phar 7.10 (3) requires a pharmacist to have written procedures regarding the administration by injection of prescription drug products and devices in the course of teaching self-administration techniques to a patient. Is the pharmacist supposed to develop the written procedures himself or herself? Are the procedures reviewed by anyone?

**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

**IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 98-187)**

TO: Senator Judy Robson, Senate Co-Chairperson
Joint Committee for the Review of Administrative Rules
Room 15 South, State Capitol
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form rules relating to pharmacists administering by injection a drug product or device in the course of teaching a patient self-administration techniques.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

SEP 02 REC'D

SEP 02 1999



Tommy G. Thompson
Governor

Marlene A. Cummings
Secretary

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Administrative Rules in Final Draft Form

Pharmacy Examining Board

Relating to: Self-Administration Techniques

Rule: Phar 7.10

Clearinghouse Rule: No. 98-187

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**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

IN THE MATTER OF RULE-MAKING : **REPORT TO THE LEGISLATURE**
PROCEEDINGS BEFORE THE : **ON CLEARINGHOUSE 98-187**
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:

These rules will have no significant impact upon state or local units of government.

IV. STATEMENT EXPLAINING NEED:

This rule-making order of the Pharmacy Examining Board creates s. Phar 7.10 to implement s. 450.035 (1r), Stats., as created by 1997 Wisconsin Act 68. The new statute authorizes pharmacists to administer by injection to patients prescribed drug products or devices in the course of teaching self-administration techniques to patients. An example is the administration of insulin to a patient for the purpose of instructing the patient on appropriate techniques for future self-administration by the patient.

Under the statute, the Pharmacy Examining Board is directed to promulgate rules establishing requirements and procedures for pharmacists desiring to engage in the administration of drugs or devices. To assist the board in this endeavor, a pharmacist advisory council was created under the statutes consisting of two pharmacists, a physician and a nurse. [Section 15.407 (6), Stats.] The statute requires the pharmacist advisory council to make a unanimous recommendation to the board respecting proposed rules, and the board is authorized to promulgate rules that are identical to those recommended by the pharmacy advisory council. [Sections 450.02 (2g) (b) and 450.025, Stats.] The rule sets forth three basic conditions that must be fulfilled in order for a pharmacist to administer by injection a prescribed drug product or device.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on January 13, 1999. John Benske, Hartland, WI, appeared in support of the rules. Written comments were received from Eric Jensen, JD, Associate Director, Government Relations, State Medical Society of Wisconsin, Madison, WI.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5.e. Section Phar 7.10 (3) requires a pharmacist to have written procedures regarding the administration by injection of prescription drug products and devices in the course of teaching self-administration techniques to a patient. Is the pharmacist supposed to develop the written procedures himself or herself? Are the procedures reviewed by anyone?

Response: Yes, the board expects a pharmacist to develop the written procedures. Outside review of the procedures adopted by a pharmacist is not required under the proposed rule.

The remaining recommendations suggested in the Clearinghouse Report were accepted in whole.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 98-187)

PROPOSED ORDER

An order of the Pharmacy Examining Board to *create* Phar 7.10, relating to pharmacists administering by injection a drug product or device in the course of teaching a patient self-administration techniques.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2) and 450.02 (2g) (b), Stats.

Statutes interpreted: s. 450.035 (1g) and (1r), Stats.

This rule-making order of the Pharmacy Examining Board creates s. Phar 7.10 to implement s. 450.035 (1r), Stats., as created by 1997 Wisconsin Act 68. The new statute authorizes pharmacists to administer by injection to patients prescribed drug products or devices in the course of teaching self-administration techniques to patients. An example is the administration of insulin to a patient for the purpose of instructing the patient on appropriate techniques for future self-administration by the patient.

Under the statute, the Pharmacy Examining Board is directed to promulgate rules establishing requirements and procedures for pharmacists desiring to engage in the administration of drugs or devices. To assist the board in this endeavor, a pharmacist advisory council was created under the statutes consisting of two pharmacists, a physician and a nurse. [Section 15.407 (6), Stats.] The statute requires the pharmacist advisory council to make a unanimous recommendation to the board respecting proposed rules, and the board is authorized to promulgate rules that are identical to those recommended by the pharmacy advisory council. [Sections 450.02 (2g) (b) and 450.025, Stats.]

These rules have been recommended to the board by a unanimous vote of the pharmacy advisory council, and have been approved for promulgation by the board in the exact and identical language and form recommended, as required under the statute.

The rule sets forth three basic conditions that must be fulfilled in order for a pharmacist to administer by injection a prescribed drug product or device. First, a pharmacist must complete

12 hours in a course of study and training approved by the American Council on Pharmaceutical Education or the board in injection techniques, emergency procedures and record keeping. This is intended to assure that a pharmacist receives appropriate training in injecting prescription drugs, as well as in the recognition of and appropriate procedures to be followed in the event of an emergency, such as an allergic reaction to the injection. The source for this requirement is that which is statutorily mandated for pharmacists to administer vaccines, under s. 450.035 (2), Stats. The board believes that similar training is necessary for a pharmacist to administer by injection a prescription drug as is the case in administering vaccines (e.g., flu shots).

The second condition is that the pharmacist would be required to carry liability insurance of not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. Again, this condition is drawn from the statutory language regarding the administration of vaccines [s. 452.035 (2t), Stats.]. The board believes it to be in the interests of the public that pharmacists carry liability insurance to the same extent for the administration by injection of prescription drugs as the legislature has required by statute for the administration of vaccines.

Third, the pharmacist would be required to adopt written procedures respecting the administration by injection of a prescription drug product or device in teaching self-administration techniques to patients. This is intended to assure uniformity in training techniques and procedures utilized by a pharmacist respecting each of his or her patients.

Finally, the rule does not apply to the administration of vaccines. However, a "Note" is created to provide the statutory reference regulating the administration of vaccines for the reader's convenience.

TEXT OF RULE

SECTION 1. Phar 7.10 is created to read:

Phar 7.10 Administration of drug products and devices other than vaccines. A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats., in the course of teaching a patient self-administration techniques except a pharmacist may not administer by injection a prescribed drug product or device unless he or she satisfies each of the following:

(1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the American council on pharmaceutical education or the board, in injection techniques, emergency procedures and record keeping.

(2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration by injection of prescribed drug products or devices in an amount that is not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.

(3) The pharmacist has written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self-administration techniques to a patient.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

(END OF TEXT OF RULE)

The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated _____ Agency _____
Chairperson
Pharmacy Examining Board

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

FINAL REGULATORY FLEXIBILITY ANALYSIS

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

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9/2/99