

CERTIFICATE

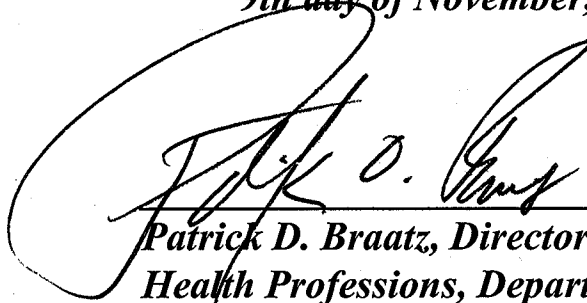
**STATE OF WISCONSIN
DEPARTMENT OF REGULATION AND LICENSING**

TO ALL WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Patrick D. Braatz, Director, Bureau of Health Professions in the Wisconsin Department of Regulation and Licensing and custodian of the official records of the Pharmacy Examining Board, do hereby certify that the annexed rules were duly approved and adopted by the Pharmacy Examining Board on the 9th day of November, 1999.

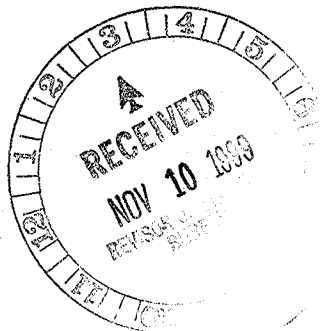
I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.

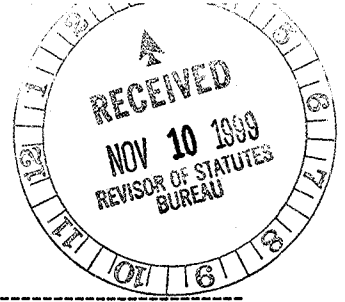
**IN TESTIMONY WHEREOF, I
have hereunto set my hand and
affixed the official seal of the
board at 1400 East Washington
Avenue, Madison, Wisconsin this
9th day of November, 1999.**



**Patrick D. Braatz, Director, Bureau of
Health Professions, Department of
Regulation and Licensing**

98-187





STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

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.

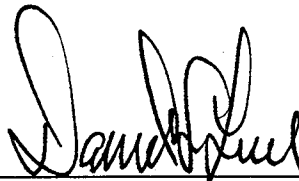
(END OF TEXT OF RULE)

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

11/9/99

Agency



Chairperson

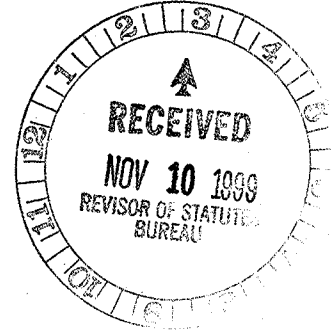
Pharmacy Examining Board

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11/3/99



State of Wisconsin
DEPARTMENT OF REGULATION AND LICENSING
CORRESPONDENCE/MEMORANDUM

DATE: November 10, 1999
TO: Gary Poulson
Assistant Revisor of Statutes
FROM: Pamela A. Haack, Paralegal
Department of Regulation and Licensing
Office of Administrative Rules
SUBJECT: Final Order Adopting Rules



Agency: Pharmacy Examining Board

Clearinghouse Rule 98-187

Attached is a copy and a certified copy of a final order adopting rules.

Please stamp or sign a copy of this letter to acknowledge receipt.

Thank you.