Clearinghouse Rule 16-079

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate s. Phar 7.10 relating to administration of drug products and devices other than vaccines.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.035 (1r) and (1t), Stats.

Statutory authority: ss. 15.08 (5) (b) and 450.02 (2g) (b), Stats.

Explanation of agency authority:

Each examining board: shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. [s. 15.08 (5) (b), Stats.]

The board shall promulgate rules that establish requirements and procedures for the administration of a drug product or device, as defined in s. 450.035(1g), by a pharmacist under s. 450.035(1r). [s. 450.02(2g)(b), Stats.]

Related statute or rule: N/A

Plain language analysis:

This proposed rule establishes requirements and procedures for a pharmacist or pharmacist intern to administer a prescribed drug product or device in order to implement 2015 Act 290. (A drug product or device does not include vaccinations.)

A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has completed a course of study and training in administration techniques.

A person who has successfully completed their third year and is enrolled in a school of pharmacy or a pharmacist licensed in another state who has applied for a Wisconsin pharmacist license may not administer a drug product or device unless they successfully complete a course of study and training in administration technique and administers the drug product or device only under the direct supervision of a pharmacist who has successfully completed the course of study.

The course of study must be approved by the Accreditation Council for Pharmacy Education or the Board. The Board will evaluate programs using criteria substantially equivalent to the criteria used by the Accreditation Council or Pharmacy Education.

After the pharmacist administers a prescribed drug product or device, the pharmacist or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system the pharmacist shares with the prescribing practitioner.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules relating to administration of drugs or devices other than vaccinations/immunizations.

Iowa: Iowa designates persons as qualified to administer drugs who are licensed pharmacists and have successfully completed a medication administration course. [657-8.32 Iowa Admin Code]

Michigan: Michigan does not have rules relating to administration of drugs or devices.

Minnesota: Minnesota does not have rules relating to administration of drugs or devices.

Summary of factual data and analytical methodologies:

The Board is implementing the language from 2015 Act 290. For the criteria for approving the course of study, the Board consulted with both the Medical Examining Board and Board of Nursing as is required pursuant to s. 450.02 (2g) (a).

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule was posted for economic comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jeffrey. Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 17, 2017 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.10 is repealed and recreated to read:

Phar 7.10 Administration of drug products and devices other than vaccines. (1) 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. After the pharmacist administers a prescribed drug product or device, the pharmacist or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

- (2) A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training, approved by the Accreditation Council for Pharmacy Education, or the board, in administration techniques.
- (3) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a prescribed drug product or device unless the person satisfies all of the following:
 - (a) Successfully completes a course of study and training in administration technique approved by the Accreditation Council of Pharmacy Education or the board.
 - (b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique approved by the Accreditation Council of Pharmacy Education or the board.
- (4) The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.

SECTION 2. EFFECTIVE DATE. 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.

(END OF TEXT OF RULE)