

STATE OF WISCONSIN
Pharmacy Examining Board

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE
PHARMACY EXAMINING BOARD

ORDER OF THE PHARMACY EXAMINING BOARD
ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS # 032-16, was approved by the Governor on April 25, 2016, published in Register 725A2 on May 9, 2016, and approved by Pharmacy Examining Board on May 19, 2016. This emergency rule as approved by the Governor on Nov. 8, 2016

ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is:

2015 Act 290 creates the ability for a person engaged in the practice of pharmacy to administer by injection a prescribed drug product or device pursuant to requirements and procedures established in the rules promulgated. This rule to implement 2015 Act 290 will create increased patient access and adherence to medications by allowing pharmacists to assist patients in the community with self-injectable medications or in the institutional setting as part of the multidisciplinary care team. Preservation of the public health, safety, and welfare necessitates putting the rule into effect prior to 2017.

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:**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 is implementing 2015 Act 290 and will not have an effect on small business.

Fiscal Estimate: This rule will not have a fiscal impact.

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.

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 publication in the Wisconsin State Journal.

(END OF TEXT OF RULE)