

[STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING: ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS #060-19, was approved by the Governor on July 29, 2019, published in Register 764A1 on August 5, 2019, and approved by the Pharmacy Examining Board on August 15, 2019. This emergency rule as approved by the Governor on September 19, 2019.

ORDER

An order of the Pharmacy Examining Board to create Phar 7.21 relating to delegate check delegate.

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:

The Pharmacy Examining Board may authorize a pilot program and grant a waiver or variance in connection with the pilot program from any rule promulgated by the Board and the pilot program may not last longer than 3 years pursuant to s. 450.02 (3r), Stats. The pilot program waives Phar 7.01(1)(c) and (d), and 7.015(3) (a) and (4), Wis. Admin. Code. Pharmacies, including those operating in hospitals, have been operating in the pilot program since October 1, 2016.

Testimony received at the public hearing held on April 12, 2019 on the permanent rule CR 19-024 included comments indicating that hospital patient care services would be negatively impacted without the rule.

CR 19-024 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3)(a), (d) and (e), Stats.

Explanation of agency authority:

The board shall adopt rules defining the active practice of pharmacy. the rules shall apply to all applicants for licensure under s. 450.05. [s. 450.02, Stats.]

The board may promulgate rules:

(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

(d) Necessary for the administration and enforcement of this chapter and ch. 961.

(e) Establishing minimum standards for the practice of pharmacy.

[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

This rule allows for the product verification to be completed by delegate-check-delegate.

Delegate-check-delegate allows a person delegated by the pharmacist to check the product verification of a product prepared by another person delegated by the pharmacist.

In order for a person to be delegated product verification, the individual must meet all of the following: be 18 years of age; completed an accredited technician training program or has a minimum of 500 hours of experience in product selection labeling and packaging; completed a didactic and practical training curriculum; and completed a validation process.

The didactic and practical training curriculum must include elements of a package label; medication and pharmacy abbreviations needed to match ordered medication with dispensed medication; common dispensing medication errors and concepts; eligible medications; policies and procedures on reporting of medication errors; overview of the pharmacy's medication use process and a practical training designed to assess the competency of the individual. The validation process requires a check of 500 product verifications over at least 5 days with an accuracy rate of at least 99.8%.

A product is eligible in institution pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In an institutional pharmacy the medication is required to be administered by a health care provider or a person authorized to administration drugs at the institution.

Product verifications can be done by delegates in community pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In a community pharmacy the medication is required to include a description of the medication on the prescription label that allows for a patient to check the accuracy of the medication.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, documentation of supervising and managing pharmacist responsibilities and dates of supervision responsibilities.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding technician-check-technician.

Iowa: Iowa has rules regarding technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and trained in technician-check-technician (including medication errors). There shall be a supervising pharmacist. The pharmacy is required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration.

Michigan: Michigan does not have rules regarding technician-check-technician.

Minnesota: Minnesota does not have rules regarding technician-check-technician.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate-check-delegate on October 1, 2016. The purpose was to study the accuracy and determine whether delegate-check-delegate improves the safety, quality or efficiency of the practice of pharmacy. The Pharmacy Examining Board determined that the procedures utilized in the pilot program were sufficient for the safety of the public and is amending the rules to allow for this practice.

The Pharmacy Examining Board also received information from the Pharmacy Society of Wisconsin's community delegate-check-delegate study.

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. This rule does not require a pharmacy to utilize delegate-check-delegate process in the pharmacy.

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 Daniel.Hereth@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, 4822 Madison Yards Way, 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 Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov.

Comments must be received on or before October 23, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.21 is created to read:

Phar 7.21 Delegate-check-delegate. (1) DEFINITIONS. In this section:

- (a) “Delegate” means a person to whom the pharmacist has delegated the task of product verification.
- (b) “Delegate-check-delegate” means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.
- (c) “Product verification” means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.
- (d) “Supervising pharmacist” means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

- (a) Is at least 18 years old.
- (b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.
- (c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:
 - 1. Elements of correct product including all of the following:
 - a. Drug name.
 - b. Strength.
 - c. Formulation.
 - d. Expiration date.
 - e. Beyond use date.
 - 2. Common dispensing medication errors and concepts including all of the following:
 - a. Wrong medication.
 - b. Wrong strength.
 - c. Wrong formulation.
 - d. Extra or insufficient quantity.
 - e. Omitted medications if utilizing unit dose or compliance packaging.
 - f. Expired medication.
 - g. Look-alike or sound-alike errors.
 - h. High-alert medications.
 - 3. Eligible medications for delegate-check-delegate.
 - 4. Organizational policies and procedures on reporting of medication errors.
 - 5. Overview of the medication use process including all of the following:
 - a. Procurement.
 - b. Ordering.
 - c. Dispensing.
 - d. Administration.

- e. Monitoring.
- 6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
 - a. Wrong drug.
 - b. Wrong strength.
 - c. Wrong formulation.
 - d. Omitted medication, if utilizing unit dose or compliance packaging.
- (d) Completed the following validation process:
 - 1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
 - 2. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.
- (e) Notwithstanding, par (a) to (d), a delegate who completed the pilot program validation process between October 1, 2016 and September 30, 2019 meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4)

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:

- 1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
- 2. Has a drug utilization review performed by a pharmacist prior to dispensing.
- 3. Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if the medications meets all of the following:

- 1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
- 2. Has a drug utilization review performed by a pharmacist prior to dispensing.
- 3. Includes a description of the medication on the prescription label that allows for a non pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

- 1. Name of the product verification delegate.
- 2. Total number of product verifications performed.
- 3. Number of product verifications audited by the pharmacist.
- 4. Percentage of product verifications audited by pharmacist.
- 5. Percentage of accuracy.
- 6. Number of product verification errors identified.
- 7. Type of error under sub. (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.

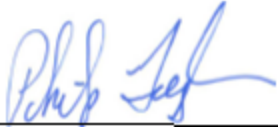
3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

SECTION 2. EFFECTIVE DATE. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated September 25, 2019

Agency 
Chair of the Pharmacy Examining Board