Clearinghouse Rule 19-024

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 create Phar 7.21 relating to delegate check delegate.

Analysis prepared by the Department of Safety and Professional Services.

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 prescription filled by another person delegated by the pharmacist.

In order for a person to be delegated to check 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, with artificially introduced error occurrences, over at least 5 days with an accuracy rate of at least 99.8%. The supervising pharmacist shall remove the artificially introduced errors prior to patient delivery.

Product verifications can be done by delegates in institution pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the packaging process results in a final package that 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 packaging process results in a final package that 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:

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, 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 April 12, 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) "Product verification" means doing a check of the accuracy and correctness of the drug product and label requirements.

(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 all of the following:

1. Elements of a package label including all of the following:
    a. Drug name.
    b. Dose.
    c. Dosage form.
    d. Control or lot number.
    e. Expiration date.
    f. Beyond use date.
2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication.
3. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong dose.
    c. Wrong dosage form.
    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.
4. Eligible medications for delegate-check-delegate.
5. Organizational policies and procedures on reporting of medication errors.
6. Overview of the organization's medication use process including all of the following:
    a. Procurement.
    b. Ordering.
    c. Dispensing.
    d. Administration.
    e. Monitoring.
7. A practical training designed to assess the competency of the delegate prior to starting the validation process.

(d) Completion of the following validation process:

1. The delegate being validated shall make a product verification on the work of another delegate 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 artificially introduce at least two occurrences of each of the following:

a. Wrong drug.

b. Wrong dose.

c. Wrong dosage form.

e. Omitted medication, if utilizing unit dose or compliance packaging.

3. The pharmacist shall ensure the artificially introduced errors in subd. 2 are removed prior to delivery.

4. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.

(3) ELIGIBLE MEDICATIONS. (a) *Institutional pharmacies.* The delegate may do the product verification if the medications meet all of the following:

1. Contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.

2. A pharmacist performs the drug utilization review under s. Phar 7.03

3. 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 if the medications meet all of the following:

1. Contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the repackaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.

2. A pharmacist performs the drug utilization review under s. Phar 7.03

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 all delegate-check-delegate product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A quality assurance log of the pharmacist's delegate-check-delegate audit shall include all of the following:

1. Name of the 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 s. Phar 7.21 (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of the delegate's previous 12 months accuracy 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 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 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.

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

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)
