STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 8

Relating to: Requirements for controlled substances

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to complete a comprehensive review of Phar 8, Requirements for Controlled Substances and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Board intends to modernize Phar 8 to bring it in line with current pharmacy standards and practices. The Board will evaluate reducing the regulatory impact on pharmacies without negatively impacting public safety.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

15.08 (5) (b) The 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.

450.02 (2) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

450.02 (3) (a) The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

450.02 (3) (b) The Board may promulgate rules establishing security standards for pharmacies.

450.02 (3) (d) The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

961.31 The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

150 hours

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies and pharmacists

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

September 26, 2018

Date Submitted

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 7.01 (3) relating to pharmacist to delegate ratios.

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:

Under current pharmacy rules, there is a one pharmacist to four delegate ratio for staffing pharmacies. Wisconsin does not credential technicians although a delegate is often referred to as a technician. This rule repeals the requirement establishing a pharmacist to technician or intern ratio.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding pharmacist to technician ratio.

Iowa: Iowa does not have rules regarding pharmacist to technician ratio.

Michigan: Michigan does not have rules regarding pharmacist to technician ratio.

Minnesota: Minnesota has a ratio of one pharmacist to two technicians except the ratio is one pharmacist to three technicians when the technicians are doing the following: intravenous admixture preparation; setting up or preparing patient specific in unit dose or modified unit dose packaging; prepacking; or compounding.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate ratios on October 1, 2016. The purpose was to study the supervision and staffing of delegates in order to determine if a minimum ratio is necessary to ensure safety, quality and efficiency of the pharmacy and allow the availability of a pharmacist to be involved in other patient care activities The Pharmacy Examining Board determined that a rule establishing a ratio was not necessary.

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 7.01 (3) is repealed.

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)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
14 March 2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7.01 (3)

4. Subject
Pharmacist to delegate ratio

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The staffing levels of delegates in a pharmacy.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the State's Economy as a Whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The pilot program revealed that a ratio is not necessary to ensure safety, quality and efficiency of the pharmacy. The benefit to removing the ratio is to allow pharmacies to determine the best staffing level for their pharmacy and allow pharmacists to involved in other patient care activities.

16. Long Range Implications of Implementing the Rule
The long range implication to removing the ratio requirement is it allows pharmacies to determine staffing levels which meet the needs of their individual pharmacies.

17. Compare With Approaches Being Used by Federal Government
None

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Minnesota has a ratio of one pharmacist to two technicians except the ratio is one pharmacist to three technicians when the technicians are doing the following: intravenous admixture preparation; setting up or preparing patient specific in unit dose or modified unit dose packaging; prepacking; or compounding.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Jessica Karls-Ruplinger
Legislative Council Acting Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 19-022

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

2. Form, Style and Placement in Administrative Code

An entry should be inserted for the rule summary's description of the analysis and supporting documents used to determine the effect on small business.

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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 7.20 relating to automated technology product verification check.

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 (2), 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 automated technology.

Automated technology (machines) can be utilized for the product verification of a prescription if the machine is located within the pharmacy, utilizes barcodes or other machine readable technology and the automated technology is validated for accuracy.

Product verifications can be done by automated technology if it 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.

The medication is required to be administered by a health care provider or a person authorized to administrater drugs at the institution.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, names of supervising pharmacist, managing and supervising pharmacist responsibilities, manufacturer's recommended maintenance and quality assurance measures, dates of all software upgrades, and documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not allow for automated technology to complete the product verification.

Iowa: Iowa allows automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. If the product is going to require further manipulation than a pharmacist is required to do the product verification prior to dispensing to a patient.

Michigan: Michigan does not allow for automated technology to complete the product verification.

Minnesota: Minnesota does not allow for automated technology to complete the product verification.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for automated technology to complete the product verification on October 1, 2016. The purpose was to study the accuracy and determine whether allowing automated technology 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.

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:

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TEXT OF RULE

SECTION 1. Phar 7.20 is created to read:

Phar 7.20 Automated technology product verification (1) DEFINITIONS. In this section product verification means doing a check of the accuracy and correctness of the drug product and label requirements.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Automated technology may perform the product verification of a prescription which meets all of the following:

(a) Located within the licensed pharmacy.

(b) Utilizes barcodes or machine readable technology to complete the product verification.

(c) The automated technology shall be validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) The automated technology shall be revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) SUPERVISING PHARMACIST RESPONSIBILITIES. A supervising pharmacist, licensed in this state, shall be identified for each technology to be accountable for the operations and outcomes

of the product verification checks. The supervising pharmacist is responsible for the product verification made by the automated technology.

(4) ELIGIBLE MEDICATIONS. The automated technology may do the product verification if the medications meet all of the following:

(a) 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.

(b) A pharmacist performs the drug utilization review under Phar 7.03

(c) Administered by an individual authorized to administer medications at the institution where the medication is administered.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification 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 automated technology 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. Names of the supervising pharmacist including the start and end date of supervision responsibilities.
3. Documentation of managing pharmacist and supervising pharmacist of responsibilities.
4. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
5. Documentation of the dates of all software upgrades.
6. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(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)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
14 March 2018

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7.20

4. Subject
Automated technology conducting product verification

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☐ No

11. Policy Problem Addressed by the Rule
This rule allows for automated technology to complete the product verficiation. The Pharmacy Examining Board initiated a pilot program on October 1, 2016 and has determined that the procedures utilized in the pilot program were sufficient for the safety of the public and increases the availability of a pharmacist for involvement in other patient care activities.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the State's Economy as a Whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit of the implementing this rule is to allow for the pharmacist to be involved in other patient care activitites.

16. Long Range Implications of Implementing the Rule
The long range implication is automated technology will complete product verifications and pharmacists will be able to focus on other patient care activities.

17. Compare With Approaches Being Used by Federal Government
None

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Iowa allows for automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. Illinois, Michigan and Minnesota do not allow for automated technology to compete the product verification.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

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STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Jessica Karls-Ruplinger
Legislative Council Acting Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 19-023

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

1. Statutory Authority

The agency should consider adding s. 227.11 (2) (a), Stats., to the statutory authority section of the rule summary.

2. Form, Style and Placement in Administrative Code

a. "Product verification" should be in quotation marks under the treatment to s. Phar 7.20 (1), in SECTION 1 of the proposed rule. Additionally, within s. Phar 7.20 (1), "the drug product" should be changed to "a drug product".

b. The treatment to s. Phar 7.20 (2), in SECTION 1 of the rule, is confusing and needs revision and reorganization. It appears the objective of the provision is to set out the requirements for automated technology, but the material appears to set out a list of requirements of a prescription. Additionally, pars. (a) to (d) do not comprise a coherent list that can follow the language "meets all of the following:" in the introduction. The same comment applies to the list in s. Phar 7.20 (4). Paragraphs (c) and (d) relate to validation of automated technology and may best be separated from pars. (a) and (b). The agency should consider clarifying what person or entity is required to validate automated technology.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. Should "of a prescription" be added after "verification" in the first sentence of the plain language analysis section of the rule summary?

b. Should "(machines)" be removed from the second sentence of the plain language analysis section of the rule summary because "automated technology" is not referred to as "machines" anywhere else in the rule?

c. The first sentence of the summary of factual data and analytical methodologies section of the rule summary is confusing. Should the word "the" before "product verification" be removed or should material be added after "product verification"?

d. A period should be placed at the end of the material in s. Phar 7.20 (2) (c) and (4) (b).

e. The treatment to s. Phar 7.20 (3) is confusing and needs revision. It is not clear what person or entity "identifies" a supervising pharmacist or what the phrase "each technology" means.

f. What is the difference between "product verification" as used throughout the proposed rule and automated technology "validation" as used in s. Phar 7.20 (2) (c) and (d)?

g. The treatment to s. Phar 7.20 (4) is confusing and needs revision. For example, should "of a prescription" be added after "product verification"? The section refers to "medications", but the term "prescriptions" is used in other parts of the rule. The agency should consider modifying the language for uniformity.

h. The treatment to s. Phar 7.20 (6) (a) 3. should be revised. Should it instead say "Documentation of the responsibilities of any managing pharmacist and supervising pharmacist"?

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)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
14 March 2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7.21

4. Subject
Delegate check delegate

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
This rule allows for a delegate to complete the product verficiation. The Pharmacy Examining Board initiated a pilot program on October 1, 2016 and has determined that the procedures utilized in the pilot program were sufficient for the safety of the public and increases the availability of a pharmacist for involvement in other patient care activities.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the State's Economy as a Whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit of the implementing this rule is to allow for the pharmacist to be involved in other patient care activitites.

16. Long Range Implications of Implementing the Rule
The long range implication is delegates may complete product verifications and pharmacists will be able to focus on other patient care activities.

17. Compare With Approaches Being Used by Federal Government
None

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Iowa allows for 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).

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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. Illinois, Michigan and Minnesota do not allow for technician-check-technician.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Jessica Karls-Ruplinger
Legislative Council Acting Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 19-024

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

2. Form, Style and Placement in Administrative Code

a. An entry should be inserted for the rule summary's description of the analysis and supporting documents used to determine the effect on small business.

b. The board should add a definition for the term "delegate-check-delegate", which is used multiple times throughout the proposed rule.

c. The board should review the rule generally to ensure that each subunit, which follows introductory material, forms a complete sentence when read with the introduction. The subunits should also use a parallel sentence structure. For example, pars. (b) and (c) (intro.) of s. Phar 7.21 (2) each begin with the word "completed", while par. (d) (intro.) begins with the phrase "completion of". The board should similarly review the sentence structure of the subunits under s. Phar 7.21 (3).

d. In s. Phar 7.21 (2) (d) 2., the designation for subpar. e. should be revised to subpar. d., in order to be sequential.

e. Because the titles are not part of the substance of the rule, s. Phar 7.21 (3) (a) (intro.) should be revised to specify that the delegate may only do product verification in an institutional pharmacy if the medications meet the listed criteria, and s. Phar 7.21 (3) (b) (intro.) should likewise be revised so that the rule text explicitly refers to community pharmacies.

f. In s. Phar 7.21 (4) (b) 7., the format of the reference to s. Phar 7.21 (2) (c) 3. should be revised to "sub. (2) (c) 3.".

4. Adequacy of References to Related Statutes, Rules and Forms

In s. Phar 7.21 (3) (a) 2. and (b) 2., the references to s. Phar 7.03 are not clear. That provision refers to prescription renewal limitations, rather than a drug utilization review. Either the terminology should be revised to be consistent, or, if a different review is intended, the cross-reference should be corrected.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 7.21 (1) (b), consider revising the sentence to specify more clearly what is intended. For example, the provision uses the phrase "accuracy and correctness", but the current rule refers to "accuracy, validity, completeness, and appropriateness" of a filled prescription, and consistent terminology should be used when possible. Is the proposed rule intended to address both accuracy and validity? And should completeness be included? Also, the "correctness of the drug product and label requirements" is not grammatically coherent. Is this intended to require a verification both that the product corresponds to the identification on the label, and that the label itself is in compliance with state and federal law requirements?

b. In s. Phar 7.21 (2) (b), it appears that the word "pharmacy" should be inserted before the phrase "technician training program", and that the word "pharmaceutical" should be inserted before the phrase "product selection".

c. In s. Phar 7.21 (2) (c) (intro.), for clarity, consider inserting the phrase "training in" before the phrase "all of the following:".

d. In s. Phar 7.21 (3) (a) 2. and (b) 2., a period should be inserted at the end of each sentence.