

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Delegate-Check-Delegate

Rule Type: Emergency

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

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. Therefore the preservation of the public health, safety and welfare necessitates an emergency rule.

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

The objective is to create a process for technicians to check technicians filling prescriptions without a final check by the pharmacist.

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:

Under current pharmacy rules, a final check of a prescription can only be performed by a pharmacist. The Pharmacy Examining Board began a pilot program for Delegate-Check-Delegate on October 1, 2016 which will end on September 30, 2019 or the promulgation of rules. The purpose of the Delegate-Check-Delegate Pilot Program is to study the accuracy of a pharmacy delegate (technician) making a final check of another delegate (technician) filling the prescription. The purpose is to increase the availability of a pharmacist for involvement in other patient care activities. The rule creates a process for delegate-check-delegate to safely complete the product verification portion of the final check of a prescription instead of a pharmacist.

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

450.02 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) 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.

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

30 hours

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

Pharmacists, Pharmacies, Delegates, Hospitals, Clinics and Patients.

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:

None

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

Date Submitted

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7.01 (3)

Relating to: Pharmacist to Delegate

Rule Type: Emergency

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

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 (3), Wis. Admin. Code. Pharmacies have been operating in the pilot program since October 1, 2016.

Without a rule in place when the pilot program expires, pharmacies will be required to hire more pharmacists to continue current operations.

CR 19-022 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption. Therefore the preservation of the public health, safety and welfare necessitates an emergency rule.

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

The objective is to amend the pharmacist to delegate ratio.

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:

Under current pharmacy rules, there is a 4 delegates per pharmacist ratio for staffing pharmacies. The Pharmacy Examining Board began a pilot program for delegate ratios on October 1, 2016 which will end on September 30, 2019 or the promulgation of rules. The purpose of the Ratio Pilot Program is to study the supervision and staffing of technicians in order to determine the minimum ratio necessary to ensure safety, quality and efficiency of the pharmacy and allow the availability of a pharmacist for involvement in other patient care activities.

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

450.02 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) 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.

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

30 hours

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

Pharmacists, pharmacies, delegates and patients.

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:

None

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

Date Submitted

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Automated Technology Final Check

Rule Type: Emergency

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

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), Wis. Admin. Code. Pharmacies have been operating in the pilot program since October 1, 2016.

Without a rule in place when the pilot program expires, pharmacies will be unable to utilize automated technology to complete the final check. This will have a negative impact on patient services.

CR 19-023 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption. Therefore the preservation of the public health, safety and welfare necessitates an emergency rule.

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

The objective is to create a process for automated technology to complete the final check of a prescription instead of a pharmacist.

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:

Under current pharmacy rules, a final check of a prescription can only be performed by a pharmacist. The Pharmacy Examining Board began a pilot program for automated technology final check on October 1, 2016 which will end on September 30, 2019 or the promulgation of rules. The purpose of the Automated Final Check Pilot Program is to study the accuracy of automated technology making a final check of the final dispensed medication. The purpose is to increase the availability of a pharmacist for involvement in other patient care activities.

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

450.02 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) 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.

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

30 hours

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

Pharmacists, Pharmacies, and Patients.

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:

None

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.

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