

## **Notice of Hearing**

The Pharmacy Examining Board announces that it will hold a public hearing on a permanent rule to amend Phar 5.01(1) and (3) and 5.04; to repeal and recreate Phar 5.05; and to create Phar 5.06 relating to renewal and reinstatement, at the time and place shown below.

### **Hearing Information**

Date: November 18, 2015  
Time: 11:00 a.m.  
Location: 1400 East Washington Avenue, Room 121C  
Madison, Wisconsin

### **Appearances at the Hearing and Submittal of Written Comments**

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to Sharon.Henes@wisconsin.gov. Comments must be received at or before the hearing to be held on November 18, 2015 to be included in the record of rule-making proceedings.

The rule may be reviewed and comments made at <http://dsps.wi.gov/Boards-Councils/Rulemaking/Public-Hearing-Comments> no later than November 18, 2015 at 11:00 a.m.

### **Initial Regulatory Flexibility Analysis**

The proposed rule will not have an effect on small businesses, as defined under s. 227.114 (1).

### **Agency Small Business Regulatory Coordinator**

Eric Esser, (608) 266-2435, Eric.Esser@wisconsin.gov

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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

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PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 5.01(1) and (3) and 5.04; to repeal and recreate Phar 5.05; and to create Phar 5.06 relating to renewal and reinstatement.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** ss. 440.08 (3) (b) and 450.08

**Statutory authority:** ss. 15.08 (5) (b), 440.08 (3) (b), and 450.02 (3) (d)

**Explanation of agency authority:**

The Pharmacy Examining Board shall promulgate rules for its own guidance and for the guidance of the profession and define and enforce professional conduct and unethical practices not inconsistent with the law relating to pharmacy.

The Pharmacy Examining Board may promulgate rules requiring the holder of a credential who fails to renew the credential within 5 years after its renewal date to complete requirements in order to restore the credential, in addition to the applicable requirements for renewal established in chapter 450, that the examining board determines are necessary to protect the public health, safety or welfare. The rules may not require the holder to complete educational requirements or pass examinations that are more extensive than the educational or examination requirements that must be completed in order to obtain an initial credential from the examining board. s. 440.08 (3) (b)

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

**Related statute or rule:**

**Plain language analysis:**

Sections 1 and 2 add home medical oxygen providers which are new license under the board's jurisdiction pursuant to 2015 Act 3. It also updates the rule to reflect there is a process for determining the renewal fee instead of the amount being listed in the statute.

Section 3 removes the unnecessary sentence stating a person who has a license reinstated may renew his or her license.

Section 4 indicates that a person with an expired license may not apply for a new license. Once a person has a license, the person either renews or reinstates a license rather than using an initial licensing process. Renewal within a 5 year period requires a renewal fee and a late fee if it is past the expiration date, and certify the completion of 30 hours of continuing education. If the renewal is after 5 years but no more than 10 years and the person has not been practicing 2000 hours in the last 24 months, the person is required to pay the renewal fee and late fee, pass the jurisprudence exam, complete 160 hours of internship for each year the license has been expired, with a cap of 1000 hours, and complete 15 hours of continuing education for each year the license has been expired or pass the NAPLEX (national pharmacy exam) with the last 2 years. If the renewal is more than 10 years and the person has not been practicing 2000 hours in the last 24 months, the person is required to pay the renewal fee and late fee, pass the jurisprudence exam, complete 1000 hours of internship and pass the NAPLEX.

Section 5 provides the requirements for reinstating a license which has not been renewed for more than 5 years with unmet disciplinary action requirements or a license which has been surrendered or revoked. A person applying for reinstatement shall provide evidence of completing any disciplinary requirements and provide evidence of rehabilitation or change in circumstances which would warrant a license to be reinstated. In addition, if the license has not been active within the last 5 years the requirements necessary for renewal after 5 years would need to be met.

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

**Comparison with rules in adjacent states:**

**Illinois:** If a license is expired for more than 5 years and the licensee has not been practicing in another state during this time, a licensee shall submit proof of completion of 30 hours of continuing education and either 600 hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to renewal or the successful completion of the Pharmacist Assessment for Remediation Evaluation. To be successful on the Pharmacist Assessment for Remediation Evaluation, the person must receive an overall score of 80 or higher, as well as a minimum score of 75 in each of the 3 content areas on the examination.

**Iowa:** If a license has been inactive for more than 5 years and the licensee has not been practicing in another state, the licensee shall do one or more of the following: (a) Successfully pass all components of the licensure examination required for initial licensure; (b) Complete 160 hours of internship for each year the pharmacist was on inactive status, not to exceed 1,000 hours; (c) Obtain one and one-half times the number of continuing education credits required for each renewal period the pharmacist was inactive; (d) Complete a Continuing Professional

Development portfolio identifying minimum of 45 learning outcomes for each renewal period the pharmacist was inactive.

**Michigan:** If a license has been expired for at least 3 years but not more than 8 years, a licensee shall complete 30 hours of continuing education within the 2 years preceding the application for renewal; pass the jurisprudence examination and complete within 6 months of renewal, not less than 200 clock hours under the personal charge of a currently licensed pharmacist. Practical pharmacy experience shall include: pharmacy administration and management; drug distribution, use and control; legal requirements; providing health information services and advising patients; pharmacist's ethical and professional responsibilities; and drug and product information. If a license has lapsed for at least 8 years, the licensee shall complete 30 hours of continuing education within the 2 years preceding the application for renewal; pass the jurisprudence examination; complete within 6 months of renewal not less than 400 clock hours under the personal charge of a currently licensed pharmacist; and pass the NAPLEX. The person may be granted a temporary, nonrenewable license to complete the practical experience.

**Minnesota:** If a license is lapsed more than 2 years and the licensee is not practicing in another state, the licensee shall complete one of the following set of requirements: Payment of back renewal fees and penalty fees up to a maximum of \$1,000; complete at least 60 hours of continuing education within the last two years; pass the jurisprudence exam; pass the NAPLEX; and complete of 400 hours of work as a pharmacist intern OR pass the jurisprudence exam, pass the NAPLEX; and complete 1,600 hours as a pharmacist intern.

#### **Summary of factual data and analytical methodologies:**

#### **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 Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

#### **Agency contact person:**

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@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 Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to Sharon.Henes@wisconsin.gov. Comments must be received at or before the hearing to be held on November 18, 2015 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. Phar 5.01 (1) is amended to read:

**Phar 5.01 Requirements.** (1) Pharmacists, pharmacies, manufacturers, ~~and~~ distributors and home medical oxygen providers licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee ~~specified in s. 440.08(2), Stats~~ as determined by the department under s. 440.03(9)(a), Stats.

SECTION 2. Phar 5.01 (3) is amended to read:

**Phar 5.01 (3)** No pharmacy, manufacturer, ~~or~~ distributor or home medical oxygen provider may operate without a current license.

SECTION 3. Phar 5.04 is amended to read:

**Phar 5.04 Renewal prohibited; relicensure.** Any person whose license is currently suspended or revoked may not renew his or her license. ~~A person whose license has been suspended or revoked and subsequently reinstated by the board, and who is otherwise qualified for renewal, may renew his or her license upon completion of a renewal form and filing of the required renewal fee.~~

SECTION 4. Phar 5.05 is repealed and recreated to read:

**Phar 5.05 Renewal.** (1) GENERAL. A person with an expired credential may not reapply for a credential using the initial application process.

(2) RENEWAL WITHIN 5 YEARS. A person renewing the license within 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and any applicable late renewal fee.

(b) Certify the completion of 30 hours of continuing education during the last biennium.

(3) RENEWAL AFTER EXPIRATION DATE. Notwithstanding par. (2), if a pharmacist fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacist's license and may require the pharmacist to pass an examination to the satisfaction of the board to restore that license.

(4) RENEWAL AFTER 5 YEARS. This subsection does not apply to license holders who have unmet disciplinary requirements. A person renewing the credential after 5 years shall do all of the following:

- (a) Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and the renewal late fee.
- (b) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin designated as the primary state.
- (c) If the person renewing the credential does not have 2000 hours of practice as a pharmacist within last 24 months of submitting the application for renewal, the person shall meet one of the following requirements:
  - 1. If the license has been expired for at least 5 years but not more than 10 years, the person shall submit evidence of all of the following:
    - a. Completion of 160 hours of internship for each year the pharmacist license was expired, not to exceed 1000 hours.
    - b. Completion of 15 hours of continuing education for each year the pharmacist license was expired or within the last two years passing the NAPLEX.
  - 2. If the license has been expired for more than 10 years, the person shall submit evidence of all of the following:
    - a. Completion of 1000 hours of internship.
    - b. Passing the NAPLEX.

SECTION 5. Phar 5.06 is created to read:

**Phar 5.06 Reinstatement.** A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

- (1) Evidence of completion of the requirements in Phar 5.05 (4) if the license has not been active within 5 years.
- (2) Evidence of completion of the disciplinary requirements, if applicable.
- (3) Evidence of rehabilitation or change in circumstances warranting reinstatement.

SECTION 6. 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.

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(END OF TEXT OF RULE)

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

Original    Updated    Corrected

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2. Administrative Rule Chapter, Title and Number

Phar 5

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3. Subject

Renewal and Reinstatement

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4. Fund Sources Affected

GPR    FED    PRO    PRS    SEG    SEG-S

5. Chapter 20, Stats. Appropriations Affected

20.165(1)(g)

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6. Fiscal Effect of Implementing the Rule

No Fiscal Effect    Increase Existing Revenues    Increase Costs  
 Indeterminate    Decrease Existing Revenues    Could Absorb Within Agency's Budget  
 Decrease Cost

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7. The Rule Will Impact the Following (Check All That Apply)

State's Economy    Specific Businesses/Sectors  
 Local Government Units    Public Utility Rate Payers  
 Small Businesses (if checked, complete Attachment A)

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8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes    No

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9. Policy Problem Addressed by the Rule

The rule clarifies and updates the requirements for renewal and reinstatement.

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10. 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 impact comments and none were received.

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11. Identify the local governmental units that participated in the development of this EIA.

None

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12. 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 and fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

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13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit is to provide license holders with clear requirements to renew and reinstate their licenses.

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14. Long Range Implications of Implementing the Rule

The long range implication is license holders are provided with clear expectations of the process to renew and reinstate their licenses.

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15. Compare With Approaches Being Used by Federal Government

None

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

In Illinois, if a license is expired for more than 5 years and the licensee has not been practicing in another state during this time, a licensee shall submit proof of completion of 30 hours of continuing education and either 600 hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to renewal or the successful completion of the Pharmacist Assessment for Remediation Evaluation. To be successful on the Pharmacist Assessment for Remediation Evaluation, the person must receive an overall score of 80 or higher, as well as a minimum score of 75 in each of the 3 content areas on the examination. In Iowa, if a license has been inactive for more than 5 years and the licensee has not been practicing in another state, the licensee

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

shall do one or more of the following: (a) Successfully pass all components of the licensure examination required for initial licensure; (b) Complete 160 hours of internship for each year the pharmacist was on inactive status, not to exceed 1,000 hours; (c) Obtain one and one-half times the number of continuing education credits required for each renewal period the pharmacist was inactive; (d) Complete a Continuing Professional Development portfolio identifying minimum of 45 learning outcomes for each renewal period the pharmacist was inactive.

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17. Contact Name

Sharon Henes

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18. Contact Phone Number

(608) 261-2377

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



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Scott Grosz**  
*Clearinghouse Director*

**Margit S. Kelley**  
*Clearinghouse Assistant Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Jessica Karls-Ruplinger**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE **15-081**

AN ORDER to amend Phar 5.01 (1) and (3) and 5.04; to repeal and recreate Phar 5.05; and to create Phar 5.06, relating to renewal and reinstatement.

Submitted by **PHARMACY EXAMINING BOARD**

10-20-2015 RECEIVED BY LEGISLATIVE COUNCIL.

11-16-2015 REPORT SENT TO AGENCY.

SG:BL

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]  
Comment Attached            YES             NO
  
2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]  
Comment Attached            YES             NO
  
3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]  
Comment Attached            YES             NO
  
4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS  
[s. 227.15 (2) (e)]  
Comment Attached            YES             NO
  
5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]  
Comment Attached            YES             NO
  
6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL  
REGULATIONS [s. 227.15 (2) (g)]  
Comment Attached            YES             NO
  
7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]  
Comment Attached            YES             NO



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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*Legislative Council Deputy Director*

### CLEARINGHOUSE RULE 15-081

#### 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. In SECTION 1 of the rule, only a single period should appear at the end of s. Phar 5.01 (1).
- b. In SECTION 4 of the rule, “Stats.” should be changed to “Stats.,”.
- c. In SECTION 4 of the rule, the phrase “Notwithstanding par. (2)” should be changed to “Notwithstanding sub. (2)”.

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

- a. In s. Phar 5.05 (1), the agency refers to an expired “credential”. Throughout the other provisions of the rule, the term “license” is used. Is it necessary to reconcile the use of these two terms?
- b. Because s. Phar 5.06 relates to reinstatement and licensees with *unmet* disciplinary requirements, is it necessary to use the phrase “if applicable” at the end of s. Phar 5.06 (2)? Under what circumstances would evidence of completion of disciplinary requirements be inapplicable?

