

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 repeal Phar 6.04 (2) and (3) (a) 2. and 3., Phar 6.04 (3) (a) 7. (b) and (c) and (4), and Phar 11; to renumber and amend Phar 6.04 (3) (a) (intro.), 1., 5., and 6.; and to amend s. Phar 5.02 (1) and (2), Phar 6.04 (1), Phar 7.04 (3) (intro.), and Phar 12.04, relating to name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.06 (1) and 450.09 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (b), (d), and 450.06 (1), Stats.

Explanation of agency authority:

Each examining 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. [s. 15.08 (5) (b), Stats.]

The board may promulgate rules relating to the distribution and dispensing of prescription drug and establishing security standards for pharmacies. [s. 450.02 (3) (a) and (b), Stats.]

The Board may promulgate rules necessary for the administration and enforcement of this chapters 450 and 961, Stats. [s. 450.02 (3) (d), Stats.]

No pharmacist may dispense at any location in this state that is not licensed as a pharmacy by the board. No person in this state may use or display the title "pharmacy," "drugstore," "apothecary," or any other title, symbol, or insignia having the same or similar meanings, except for a place of practice which is licensed under this section as a pharmacy by the board. [s. 450.06 (1), Stats.]

Related statute or rule: N/A

Plain language analysis:

The Pharmacy Examining Board identified the following rules in its 2019 report filed with the Joint Committee for Review of Administrative Rules pursuant to s. 227.29, Stats.

Phar 5.02 is revised to delete obsolete or unnecessary provisions to require the notification to the Board regarding name or address change to be submitted in writing.

Phar 6.04 is revised to delete economically burdensome requirements and requirements which do not correspond with the evolving types of pharmacies.

Phar 7.04 (3) is revised to correct a typographical error occurring in CR 19-145 related to which should refer to Schedule III – V drugs instead of Schedule III – IV drugs. The omission of Schedule V creates inconsistency with the federal law and confusion for pharmacists.

Ch. Phar 11 is repealed as it is duplicative and unnecessary.

Phar 12.04 is revised as the federal standards referenced have been superseded.

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

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.610 outlines the standards for pharmacy structure/equipment standards. The section does require a locked area for drugs. However, Illinois does not identify professional service area square footage requirements or signage requirements.

Iowa: The complete Iowa Board of Pharmacy rules are contained in 657 Iowa Administrative Code. The Iowa Pharmacy Practice Act is codified under administrative code chapter 155A, specifically related to licensed pharmacies under s. 155A.13. Rules do require a locked area for drugs. However, there are no comparable requirements for professional service area square footage or signage.

Michigan: Michigan administrative code MCL 338.536 for housing of pharmacies specifically requires pharmacies to have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that it includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist on duty, workspace must be increased by not less than 4 square feet and pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling of substantial construction and must be securely lockable. There do not appear to be requirements for signage.

Minnesota: The Minnesota Administrative Code chapter 6800 related to pharmacies and pharmacists, provides the rules for the standards for pharmacies. Specifically, Minnesota Administrative Code section 6800.0700 provides minimum requirements for pharmacies. The pharmacy space requirements include the pharmacy must: contain more than 250 square feet in the dispensing and drug storage area; maintain a prescription dispensing counter at least 18 inches deep that provides 2 linear feet; maintain an aisle behind the prescription dispensing counter at least 36 inches wide, extending the full length of the counter; be surrounded by a continuous partition or wall extending from the floor to the permanent ceiling; and contain doors capable of being securely locked. There do not appear to be requirements for signage.

Summary of factual data and analytical methodologies:

The Board conducted a full review of its administrative codes in compliance with the Legislative Report to the Joint Committee of Review of Administrative Rules under s. 227.29, Stats. The items in this rule project are a result of that review.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

A fiscal estimate and economic impact analysis are 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:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (608) 267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, 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 December 2, 2021, at a time to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 5.02 (1) and (2) are amended to read:

Phar 5.02 (1) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's name has been legally changed, within 30 days of the change.

(2) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's address has been changed, within 30 days of the change.

SECTION 2. Phar 6.04 (1) is amended to read:

Phar 6.04 (1) PROFESSIONAL SERVICE AREA. ~~The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy building is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present while the professional service area is closed, the professional service area shall be secured as specified in sub. (3). A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service plan varies from the requirement.~~

SECTION 2. Phar 6.04 (2) is repealed.

SECTION 3. Phar 6.04 (3) (a) (intro.), and 1. are renumbered Phar 6.04 (3) (intro.) and (am) and are amended to read:

Phar 6.04 (3) (intro.) ~~PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT~~ REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED

~~Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if~~ When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements are met:

(am) A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by ~~unlicensed~~ unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

SECTION 4. Phar 6.04 (3) (a) 2. and 3. are repealed.

SECTION 5. Phar 6.04 (3) (a) 5. and 6. are renumbered Phar 6.04 (3) (bm) and (cm) and amended to read:

Phar 6.04 (3) ~~(a) 5.~~(bm) Signs of reasonable size are posted at ~~the entrance of the building and~~ the professional service area which prominently displaying display the hours the pharmacist will ~~be on duty~~ professional services are available.

~~6.~~(cm) The manner in which the telephone is answered does not imply that the ~~location is, at that time, operating as a pharmacy~~ professional services are available.

SECTION 6. Phar 6.04 (3) (a) 7., (b) and (c) and (4) are repealed.

SECTION 7. Phar 7.04 (3) (intro.) is amended to read:

7.04 (3) (intro.) The transfer of original prescription information for a controlled substance listed in Schedule III – ~~IVV~~ shall meet the following requirements:

SECTION 8. Chapter Phar 11 is repealed.

SECTION 9. Phar 12.04 is amended to read:

Phar 12.04 Inspections. Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets ~~the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985)~~ federal and state laws and regulations.

SECTION 10. 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)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<p>1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected</p>	<p>2. Date September 22, 2021</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) Phar 5, 6, 7, 11, 12</p>	
<p>4. Subject Name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction</p>	
<p>5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S</p>	<p>6. Chapter 20, Stats. Appropriations Affected 20.165(1)(g)</p>
<p>7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input checked="" type="checkbox"/> Could Absorb Within Agency's Budget</p>	
<p>8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)</p>	
<p>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0</p>	
<p>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)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule The objective of the rule is to repeal or modify provisions of the rule identified in the Pharmacy Examining Board's report to the Joint Committee for Review of Administrative Rules pursuant to s. 227.29, Stats. In addition, the rule will make a typographical correction in Phar 7.04 (3).</p>	
<p>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. The rule was posted for 14 days on the Department of Safety and Professional Services' website to solicit comments on the potential economic impact. No comments were received.</p>	
<p>13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.</p>	
<p>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) No economic or fiscal impacts are anticipated for specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole. A total of \$120.32 in one time costs are anticipated to be absorbed within the operating budget of the Department of Safety and Professional Services.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit to implementing the rule is providing updates reflecting current pharmacy practice. If the rule is not implemented, it will continue to provide outdated references and terminology and reflect practices that are no longer current.</p>	
<p>16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule is updated references and terminology and reflecting current pharmacy practice.</p>	
<p>17. Compare With Approaches Being Used by Federal Government</p>	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

None

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

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.610 outlines the standards for pharmacy structure/equipment standards. The section does require a locked area for drugs. However, Illinois does not identify professional service area square footage requirements or signage requirements.

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19. Contact Name

Nilajah Hardin, Administrative Rules Coordinator

20. Contact Phone Number

(608) 267-7139

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

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
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