

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 s. Phar 6.075 relating to temperature and humidity in pharmacies.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.09 (3) and (4), Stats.

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

Explanation of agency authority:

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

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

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

450.02(3)(e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

The board shall prescribe, by rule, minimum standards of professional and technical equipment [s. 450.09 (3), Stats.]

Related statute or rule: N/A

Plain language analysis:

Section 1 creates a section on temperature and humidity. The requirements include: drugs being stored at appropriate temperature and conditions based upon the manufacturer recommendation or an official pharmaceutical compendium; the pharmacy having a temperature and humidity

recording device within the storage space; to monitor at least once per business day the temperature of the refrigerator, freezer and pharmacy as well as obtaining a minimum and maximum temperature over the course of the time the pharmacy is closed; to maintain the records for a minimum of 5 years; and for the pharmacist to use professional judgement to determine whether a drug is safe to be dispensed.

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

Comparison with rules in adjacent states:

Illinois: Illinois requires pharmacies to maintain temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing. [Section 1330.610, IL Admin Code]

Iowa: Iowa does not have rules relating to temperature or humidity in pharmacies. Wholesale pharmacies are required to have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space equipment and security conditions.

Michigan: Michigan does not have rules relating to temperature or humidity in pharmacies.

Minnesota: Minnesota does not have rules relating to temperature or humidity in pharmacies.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board recognized a rule was necessary to ensure drugs are properly stored.

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

This rule was posted for economic comments for 14 days and none were received. Maintaining pharmaceuticals at the correct temperature and humidity is the current minimum standard of the profession and should not have an economic impact on pharmacies.

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 Jeffrey.Weigand @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, 1400 East Washington Avenue, Room 151, 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 Board Services, 1400 East Washington Avenue, Room 151, 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 14, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 6.075 is created to read:

Phar 6.075 Temperature; Humidity. (1) DEFINITIONS. In this section:

- (a) Business day is a day the pharmacy is open for business.
- (b) Dry place means a place that does not exceed 40% average relative humidity at 68 degree Fahrenheit or the equivalent water vapor pressure at other temperatures.
- (c) Freezer means a place in which the temperature is maintained between -13 and 14 degrees Fahrenheit.
- (d) Mean kinetic temperature means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.
- (e) Refrigerator means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place, according to the manufacturer recommendation or an official pharmaceutical compendium.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature over the course of the time a pharmacy is closed shall be obtained.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgement, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

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)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

Phar 6.075

3. Subject

Temperature and humidity in pharmacies

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

20.165(1)(g)

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

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)

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

Yes No

9. Policy Problem Addressed by the Rule

Currently there are not rules relating to the temperature and humidity requirements for a pharmacy. Pharmaceuticals need to be stored, compounded or maintained in the correct environment in order to ensure the product quality, safety and efficiency.

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 for 14 days and none were received.

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

None.

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

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

The proposed rule addresses the temperature and humidity requirements for pharmacies to ensure the integrity of the pharmaceuticals prior to dispensing.

14. Long Range Implications of Implementing the Rule

The rules would ensure the pharmaceuticals are stored, compounded or maintained in the correct environment.

15. Compare With Approaches Being Used by Federal Government

None

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

Illinois requires pharmacies to maintain temperature within the proper storage of drugs. Iowa does not have rules regarding temperature or humidity for pharmacies but does for wholesale pharmacies. Michigan and Minnesota do not have rules relating to temperature or humidity of pharmacies.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

17. Contact Name

Sharon Henes

18. Contact Phone Number

(608) 261-2377

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:
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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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