



PHARMACY EXAMINING BOARD
Contact: Dan Williams (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison, WI 53703
December 14, 2016

Notice: The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the action and deliberation of the Board.

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. **Adoption of Agenda (1-3)**
- B. **Approval of Minutes of November 3, 2016 (4-7)**
- C. **8:30 A.M. Public Hearing on Clearinghouse Rule 16-072 Relating to Home Medical Oxygen Providers (8-26)**
 - 1) Review and Respond to Clearinghouse Report and Public Hearing Comments (9-19)
- D. **8:30 A.M. Public Hearing on Clearinghouse Rule 16-073 Relating to Temperature and Humidity in Pharmacies (8-26)**
 - 1) Review and Respond to Clearinghouse Report and Public Hearing Comments (20-26)
- E. **Legislation/Administrative Rule Matters – Discussion and Consideration**
 - 1) Update on Legislation and Pending or Possible Rulemaking Projects
- F. **Administrative Updates – Discussion and Consideration**
 - 1) Staff Updates
 - 2) Board Member – Term Expiration Date
 - a. Grace Degner – 7/1/2018 (*Appointed, not yet confirmed*)
 - b. Franklin LaDien – 7/1/2016 (*Reappointed, not yet confirmed*)
 - c. Terry Maves – 7/1/2018
 - d. Thaddeus Schumacher – 7/1/2019
 - e. Kristi Sullivan – 7/1/2016 (*Reappointed, not yet confirmed*)
 - f. Philip Trapskin – 7/1/2017
 - g. Cathy Winters – 7/1/2017
- G. **Informational Items – Discussion and Consideration**
- H. **Items Received After Preparation of the Agenda**
 - 1) Introductions, Announcements and Recognition
 - 2) Election of Board Officers
 - 3) Appointment of Board Liaisons
 - 4) Administrative Updates
 - 5) Education and Examination Matters

- 6) Credentialing Matters
- 7) Practice Matters
- 8) Legislation/Administrative Rule Matters
- 9) Informational Items
- 10) Disciplinary Matters
- 11) Presentations of Petitions for Summary Suspension
- 12) Petitions for Designation of Hearing Examiner
- 13) Presentation of Proposed Stipulations, Final Decisions and Orders
- 14) Presentation of Proposed Final Decision and Orders
- 15) Presentation of Interim Orders
- 16) Petitions for Re-Hearing
- 17) Petitions for Assessments
- 18) Petitions to Vacate Orders
- 19) Requests for Disciplinary Proceeding Presentations
- 20) Motions
- 21) Petitions
- 22) Appearances from Requests Received or Renewed
- 23) Speaking Engagement(s), Travel, or Public Relations Request(s)
- 24) Division of Legal Services and Compliance (DLSC) Matters
- 25) Prescription Drug Monitoring Program Information
- 26) Consulting with Legal Counsel
- 27) Liaison Report(s)
 - a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Franklin LaDien
 - b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
 - c. Credentialing Liaison(s): Terry Maves, Cathy Winters
 - d. Digest Liaison: Philip Trapskin
 - e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
 - f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
 - g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters
 - h. PHARM Rep to State Council on Alcohol and Other Drug Abuse (SCAODA): Kristi Sullivan
 - i. Pharmacy Rules Committee: Thaddeus Schumacher, Franklin LaDien, Philip Trapskin, Kristi Sullivan
 - j. Professional Assistance Procedure (PAP) Liaison: Franklin LaDien
 - k. Screening Panel: Cathy Winters, Kristi Sullivan, Philip Trapskin
 - l. Pilot Program Report Liaison(s): Philip Trapskin, Cathy Winters

I. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

J. Deliberation of Items Received After Preparation of Agenda

- 1) Education and Examination Matters
- 2) Credentialing Matters
- 3) Disciplinary Matters
- 4) Monitoring Matters
- 5) Professional Assistance Procedure (PAP) Matters
- 6) Petitions for Summary Suspension
- 7) Petitions for Designation of Hearing Examiner
- 8) Proposed Stipulations, Final Decisions and Orders

- 9) Administrative Warnings
- 10) Review of Administrative Warnings
- 11) Proposed Final Decisions and Orders
- 12) Orders Fixing Costs/Matters Related to Costs
- 13) Case Closings
- 14) Proposed Interim Orders
- 15) Petitions for Assessments and Evaluations
- 16) Petitions to Vacate Orders
- 17) Remedial Education Cases
- 18) Motions
- 19) Petitions for Re-Hearing
- 20) Appearances from Requests Received or Renewed

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

K. Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate

ADJOURNMENT

The Next Scheduled Meeting is January 17, 2017.

**PHARMACY EXAMINING BOARD
MEETING MINUTES
NOVEMBER 3, 2016**

PRESENT: Grace Degner, Franklin LaDien, Terry Maves, Thaddeus Schumacher, Kristi Sullivan, Philip Trapskin, Cathy Winters

STAFF: Dan Williams – Executive Director, Sharon Henes – Administrative Rules Coordinator, Nifty Lynn Dio – Bureau Assistant, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 10:37 a.m. A quorum of seven (7) members was confirmed.

ADOPTION OF AGENDA

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 22, 2016

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to approve the minutes of September 22, 2016 as published. Motion carried unanimously.

ADMINISTRATIVE UPDATES

Possible Change to the January 19, 2017 Board Meeting Date

MOTION: Terry Maves moved, seconded by Franklin LaDien, to change the January 19, 2017 meeting date to January 17, 2017. Motion carried unanimously.

PILOT PROGRAM MATTERS

List of Requests for Pilot Program Approval

MOTION: Cathy Winters moved, seconded by Kristi Sullivan, to acknowledge the recommendation of DSPS staff to approve the application of the following Pilot Programs:

1. Institution Tech-Check-Tech Pilot Program
 - a. Stockbridge-Munsee Health and Wellness – Bowler
 - b. St. Clare's Hospital – Weston
2. Pharmacy Technician Ratio Pilot Program
 - a. Stockbridge-Munsee Health and Wellness – Bowler
 - b. UW Madison Scholl of Pharmacy - Madison
3. Automated Technology Final Check Pilot Program
 - a. Stockbridge-Munsee Health and Wellness – Bowler

Motion carried unanimously.

CLOSED SESSION

MOTION: Cathy Winters moved, seconded by Terry Maves, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). The Chair read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Grace Degner-yes; Franklin LaDien-yes; Terry Maves-yes; Thaddeus Schumacher-yes; Kristi Sullivan-yes; Philip Trapskin-yes; Cathy Winters-yes. Motion carried unanimously.

At this time, all external communication contacts will be terminated for purposes of going into Closed Session.

The Board convened into Closed Session at 11:53 a.m.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Terry Maves, to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 2:44 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Kristi Sullivan moved, seconded by Terry Maves, to affirm all motions made in closed session. Motion carried unanimously.

DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warning(s)

16 PHM 003 – B.R.O.

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to issue an Administrative Warning in the matter of 16 PHM 003 (B.R.O.). Motion carried unanimously.

(Thaddeus Schumacher recused himself and left the room for deliberation and voting in the matter of DLSC Case No. 16 PHM 003 against B.R.O.)

15 PHM 169 – Brad R. Spross

MOTION: Terry Maves moved, seconded by Franklin LaDien, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Brad R. Spross, DLSC case number 15 PHM 169. Motion carried unanimously.

16 PHM 078 – Christopher M. Kachel, R.Ph.

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to reject the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Christopher M. Kachel, R.Ph., DLSC case number 16 PHM 078. The Board directs the case advisor to work with DLSC to change the terms of the Order as discussed by the Board.
Motion carried unanimously.

Case Closings

MOTION: Kristi Sullivan moved, seconded by Franklin LaDien, to close the DLSC cases for the reasons outlined below:

1. 15 PHM 063 (R.D.) – Prosecutorial Discretion (P2)
2. 15 PHM 126 (R.H. and W.P.) – Insufficient Evidence
3. 15 PHM 210 (M.P.C. and T.R.) – Insufficient Evidence
4. 16 PHM 029 (V.P.C. and J.D.) – Insufficient Evidence
5. 16 PHM 030 (Y.O.P. and J.J.) – Insufficient Evidence
6. 16 PHM 031 (M.C.R. and D.Z.) – Insufficient Evidence
7. 16 PHM 032 (P.R.N. and M.K.) – Insufficient Evidence

Motion carried unanimously.

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to request DLSC to forward the physician in Case No. 15 PHM 063 to the Medical Examining Board Screening Panel. Motion carried unanimously.

Monitoring

Allan Mailloux, R.Ph. – Requesting Full Licensure

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to grant the request of Allan Mailloux, R.Ph. for full licensure. Motion carried unanimously.

Ryan J. Nelson, R.Ph. – Requesting Full Licensure

MOTION: Terry Maves moved, seconded by Philip Trapskin, to grant the request of Ryan J. Nelson, R.Ph. for full licensure. Motion carried unanimously.

DELIBERATION ON CREDENTIALING MATTERS

Application Review

Chad Ronnebaum – Pharmacist Application

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to record that the Board has reviewed the prior discipline of Chad Ronnenbaum and finds it is not a bar to licensure. The Board approves the Pharmacist application for licensure of Chad Ronnebaum, once all requirements are met Motion carried unanimously.

Thomas Welke – Pharmacist Renewal Application

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to record that the Board has reviewed the criminal background of Thomas Welke and finds it is not a bar to licensure renewal. The Board approves the Pharmacist Renewal application of Thomas Welke, once all requirements are met. Motion carried unanimously.

(Franklin LaDien and Terry Maves recused themselves and left the room for deliberation and voting in the matter of the application of Thomas Welke)

CONSULT WITH LEGAL COUNSEL

15CV94 Pufall v. Wisconsin Pharmacy Examining Board

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to request the Executive Director and Board Chair work to maintain a summary document of Board Motions to assist the Board. Motion carried unanimously.

MOTION: Kristi Sullivan moved, seconded by Terry Maves, to record that the Board strenuously disagrees with the Court Decision in Ashland County case 2015CV94, Pufall v. Wisconsin Pharmacy Examining Board, that the applicant meets the requirements for Pharmacist Licensure in the State of Wisconsin. However, the Board recognizes and respects the authority of the court, and will comply with the Court Order dated August 10, 2016. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to record that the Board concurs with the Department's current process of having the Board Legal Counsel represent the Board in credentialing denial proceedings. Motion carried unanimously.

ADJOURNMENT

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 3:02 p.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 5 December 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 14 December 2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Public Hearing on Clearinghouse Rule 16-072 relating to home medical oxygen providers. Review and respond to Clearinghouse Report and Public Hearing comments. Public Hearing on Clearinghouse Rule 16-073 relating to temperature and humidity in pharmacies. Review and respond to Clearinghouse Report and Public Hearing comments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Hold Public Hearings at 8:30 a.m. Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.			
11) Authorization <div style="text-align: center; font-family: cursive; font-size: 1.2em; margin-bottom: 10px;"><i>Sharon Henes</i></div> <hr/> <div style="display: flex; justify-content: space-between;"> Signature of person making this request Date </div> <hr/> <div style="display: flex; justify-content: space-between;"> Supervisor (if required) Date </div> <hr/> <div style="display: flex; justify-content: space-between;"> Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date </div>			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

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 ch. Phar 14 relating to home medical oxygen providers.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.076

Statutory authority: ss. 15.08 (5) (b), 450.02 (d) and 450.076 (4), Stats.

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

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

The Pharmacy Examining Board shall promulgate rules implementing this section. The rules shall include rules governing the professional conduct of licensed providers and their employees and agents. [s. 450.076 (4), Stats.]

Related statute or rule: N/A

Plain language analysis:

This rule establishes rules for home medical oxygen providers.

An applicant shall submit an application, fee and evidence of accreditation by a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) accreditation organization recognized by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Standards of Professional Conduct include:

- Maintain accreditation status.
- Comply with all transportation rules and regulations regarding transporting oxygen.
- Comply with the Food and Drug Administration regarding transporting medical oxygen systems.
- Demonstrate that medical grade oxygen purity standards are met.
- Meet safety inspection requirements.
- Maintain recall procedures.
- Comply with maintenance and cleaning requirements.
- Implement a comprehensive preventative maintenance program.
- Maintain repair logs.
- Ensure accurate calibration.
- Provide counseling for use of equipment, safety precautions, emergency and routine contact procedures and written instructions for the operation of the equipment.
- Develop, implement and document a written plan of services in the patient record.
- Maintain all home medical oxygen records for a period of five years.

Summary of, and comparison with, existing or proposed federal regulation:

None.

Comparison with rules in adjacent states:

Illinois: Illinois licenses home medical equipment and services providers. Medical oxygen is considered by Illinois to be home medical equipment. Applicants are required to submit an application; fee and certify that the business: maintains a physical facility and medical equipment inventory; records of education training, experience and continuing education; maintains patient records; establishes and maintains equipment management and personnel policies; complies with state and federal laws applicable to the type of services provided; and provides access to emergency services 24 hours a day, 7 days a week for life sustaining home medical equipment and services. Unprofessional conduct includes: discrimination; failing to offer all facts regarding services or equipment to the client prior to administration of services; failing to protect the privacy of patient information and disclosing such information without proper authorization; performing or allowing employees to perform services beyond their scope of practice and competency; failing to establish and maintain client records; and submission of fraudulent claims for services to any person or entity. The Department also incorporates by reference the Code of Ethics approved by the National Association for Medical Equipment Services.

Iowa: In Iowa, medical oxygen is within the scope of a Pharmacy Wholesaler license

Michigan: In Michigan, medical oxygen is within the scope of a Manufacturer and Wholesaler license.

Minnesota: Minnesota requires every person or establishment selling or distributing legend medical gases that is not a pharmacy or practitioner to annually register. Registration requires an application and filing fee. Legend medical gases distributed or sold at retail shall only be to a patient on a basis of a prescription or to a hospital, practitioner, hospital, or other person or institution licensed to possess the drugs for use in the usual course of practice. Legend gases shall have the manufacturer's intact federally required labeling. Records must be maintained for at least 2 years.

Summary of factual data and analytical methodologies:

This rule implements 2015 Act 3. The Board reviewed laws of various states that license suppliers of medical oxygen.

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

This rule was posted for economic impact comments and none were received.

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 Board Services, 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 Policy Development, 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. Chapter Phar 14 is created to read:

Chapter Phar 14
HOME MEDICAL OXYGEN PROVIDERS

Phar 14.01 Application. Each applicant for licensure as a home medical oxygen provider shall submit all of the following:

- (1) Submits an application for licensure on a form provided by the board.
- (2) Pays the fee specified in s. 440.05 (1).
- (3) Evidence of accreditation by an organization deemed an accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) by the United States department of health and human services, centers for medicare and medicaid services.

Phar 14.02 Standards of Professional Conduct. Licensed home medical oxygen providers and their employees and agents shall do all of the following:

- (1) Maintain accreditation status by an organization deemed an accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) by the United States department of health and human services, centers for medicare and medicaid services.
- (2) Comply with all transportation rules and regulations regarding transporting oxygen in cylinder or liquid form.
- (3) Comply with the food and drug administration regarding transporting medical oxygen systems.
- (4) Demonstrate that oxygen provided to cylinder or liquid form meets purity standards for medical grade oxygen.
- (3) Meet safety inspection requirements including all of the following:
 - (a) Maintain documentation demonstrating each piece of oxygen or respiratory equipment has been checked, is free of defect and operates within the manufacturer's specifications.
 - (b) Equipment shall not be modified to the extent that the modification may reasonably cause harm.
 - (c) Maintain all electrical components so that they do not present a fire or shock hazard.
 - (d) Ensure that all appropriate warning labels, including tags, are present on the equipment provided.
- (6) Maintain recall procedures including all of the following:
 - (a) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered.
 - (b) Maintain a tracking system for all medical oxygen and gas delivered.
 - (c) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated.
 - (d) Maintain records for equipment that requires food and drug administration tracking.
- (7) Comply with the all of the following maintenance and cleaning requirements:

- (a) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up.
 - (b) Maintain an established protocol for cleaning and disinfecting equipment which address both aerobic and anaerobic pathogens.
 - (c) Maintain a material safety data sheet on file for solutions and products used in cleaning and disinfecting procedures.
 - (d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment.
 - (e) Clean and disinfect equipment according to manufacturers' specifications.
 - (f) Instruct the patient on proper cleaning techniques as specified by the manufacturer.
- (8)** Implement a comprehensive preventative maintenance program which includes all of the following:
- (a) Procedures for problem reporting, tracking, recall and resolution.
 - (b) Performance of service as specified by the manufacturer and the documentation of such performance in the service records.
 - (c) Routine inspection, service, and maintenance of equipment located in the patient's or customer's residence according to manufacturer's specifications.
- (9)** Maintain repair logs to document repair and maintenance of equipment, including oxygen concentrators, infant monitors and mechanical ventilators. The repair log shall include all of the following:
- (a) Type of equipment.
 - (b) Manufacturer.
 - (c) Model.
 - (d) Serial number.
 - (e) Date of repair.
 - (f) Specific repair made.
 - (g) Name of person or company performing the repair.
- (10)** Maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
- (11)** Provide counseling including all of the following:
- (a) Utilize orientation checklists for review of all of the following:
 1. Instructions for use of the equipment.
 2. Safety precautions.
 3. Cleaning procedures.
 4. Maintenance procedures.
 5. Return demonstrations on back up oxygen systems.
 - (b) Instruct the patient about emergency and routine contact procedures.
 - (c) Deliver and review written instruction materials to ensure that the patient receives information regarding the operation of the equipment.
- (12)** Develop, implement and document a written plan of services in the patient record, including an assessment of the safety of the home environment, the caregiver or patient ability to comply with the prescription and the caregiver or patient ability to operate and clean the equipment as instructed.
- (13)** Maintain all required home medical oxygen records for a period of 5 years.

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 14

3. Subject

Home medical oxygen providers

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

This rule implements 2015 Act 3 by establishing rules for home medical oxygen suppliers.

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 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 does not have an economic or fiscal impact on specific businesses, business sectors, public utility payers, local governmental units or the State's economy as a whole.

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

The benefit is implementing 2015 Act 3 by creating licensure requirements and rules to govern the professional conduct of licensed providers.

14. Long Range Implications of Implementing the Rule

Home medical oxygen suppliers will be able to dispense oxygen without being a pharmacist or practitioner.

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 licenses home medical equipment and services providers which includes medical oxygen providers. Minnesota requires a registration for persons or establishments selling or distributing legend medical gases that are not a pharmacy or practitioner. Iowa includes medical oxygen within the scope of pharmacy wholesaler licensure. Michigan includes medical oxygen within the scope of a manufacturer and wholesaler licensure.

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:
-

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

Margit Kelley
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

CLEARINGHOUSE RULE 16-072

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

a. A citation to s. 450.076 (3) (c), Stats., should be added to the rule summary’s listing of statutory authority and to the explanation of agency authority.

b. Section 450.076 (4), Stats., requires the board to promulgate rules governing the professional conduct of licensed providers and their employees and agents. While s. Phar 14.02 is titled “Standards of Professional Conduct”, it does not appear to include a code of ethical responsibilities. Compare, for example, the standards of professional conduct given in s. Phar 10.03, for the types of ethical responsibilities. That section identifies a number of actions as unprofessional conduct, such as falsifying records, disclosing confidential patient information, and aiding or abetting unlicensed practice. The board should review the proposed rule to ensure that it is complying with this requirement.

2. Form, Style and Placement in Administrative Code

a. In s. Phar 14.01 (2), a reference to “, Stats.” should be inserted after the citation to “s. 440.05 (1)”. [s. 1.07 (2) (Table), Manual.]

b. In ss. Phar 14.01 (3) and 14.02 (1), the parenthetical reference to “(DMEPOS)” should be removed. If the acronym is intended to be a defined term that can be used in place of the written-out phrase, a definition for the acronym should be created in s. Phar 1.02 or at the beginning of ch. Phar 14 and the written-out phrases should be removed. [s. 1.01 (6) and (7), Manual.]

c. In s. Phar 14.02, consider reorganizing and renaming the section. The title “Standards of Professional Conduct” suggests a code of ethical responsibilities, but most of the included items are standards of practice or other requirements. For example, sub. (1) could be placed in its own section with the title “Accreditation Requirement”. The other subsections could be reviewed to determine if they could be grouped into related requirements and placed in separate sections for duties and practice requirements, such as “Compliance with State and Federal Regulations”, “Quality and Safety Standards”, “Patient Plans”, and “Records”.

d. In s. Phar 14.02, there appears to be a typographical error that mistakenly labels sub. (5) as a second sub. (3).

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

a. In s. Phar 14.02 (2), the rule should identify whether the source of the “transportation rules” is the U.S. Department of Transportation, the Wisconsin Department of Transportation, or both. Consider adding references to specific provisions of the U.S. Code, Code of Federal Regulations, or transportation provisions of the Wisconsin Administrative Code. [s. 1.07 (1) (a) and (3), Manual.]

b. In s. Phar 14.02 (3), it appears that “U.S.” should be inserted before the phrase “food and drug administration”, and that the phrase “rules and regulations” should be inserted after the word “administration”. Consider adding references to specific provisions of the U.S. Code or Code of Federal Regulations. [s. 1.07 (1) (a) and (3), Manual.]

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

In s. Phar 14.02, the introductory material for subs. (5), (6), and (11) use the phrase “including all of the following”. That phrase suggests that the list is not exhaustive and that other unlisted items may be part of that list. Consider revising each instance of the phrase to “all of the following” (without the word “including”), and, if appropriate in the provision, adding a final paragraph for “such other procedures as may be relevant”. [ss. 1.01 (9) (f) and 1.03 (3), Manual.]

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:
-

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
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Margit Kelley
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

CLEARINGHOUSE RULE 16-073

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

In s. Phar 6.075 (1), defined terms should be identified using quotation marks. [s. 1.01 (7) (Example), Manual.]

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

a. In its enumeration of statutory authority, the board appears, based on its citations in the explanation of authority, to omit reference to s. 450.09 (3), Stats.

b. There is a typographical error in the last line of the plain language analysis; the reference to “sae” should be changed to “safe”.

c. In s. Phar 6.075 (6), “judgment” should be substituted for “judgement”.