

Clearinghouse Rule 16-072

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)
