

APA-1
07/04

**TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION**

Control No. _____ Department or Agency The Board of Home Medical Equipment

Rule No. 473-X-1-01

Rule Title: Definitions

_____ New X Amend _____ Repeal _____ Adopt by Reference _____

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer Brandy L. Benken
Date 4-23-14

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07/04

Board of Home Medical Equipment

NOTICE OF INTENDED ACTION

AGENCY NAME:

Board of Home Medical Equipment

RULE NO. & TITLE:

473-X-1-.01 Definitions

INTENDED ACTION:

To amend Rules and Regulations.

SUBSTANCE OF PROPOSED ACTION:

The Board of Home Medical Equipment proposes to adopt an Administrative Code or Rules and Regulations under which to operate.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

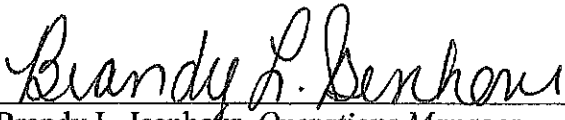
Written comments, views, or arguments will be received by the Board of Home Medical Equipment until 4:30 p.m. on July 3, 2014. Comments should be directed to Paula McCaleb, Executive Director, at Post Office Box 240636, Montgomery, AL 36124-0636, or via fax at 334-215-3457.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

July 3, 2014

CONTACT PERSON AT AGENCY:

Brandy L. Isenhour
334.215.3474


Brandy L. Isenhour, Operations Manager

473-X-1-.01. Definitions.

(1) Applicant means an individual applicant in the case of a sole proprietorship, or any officer, director, agent, managing employee, general manager, or person in charge, or any partner or shareholder having an ownership interest in the corporation, partnership, or other business entity.

(2) Board means the Board of Home Medical Equipment ~~Services Providers~~, as established by the Code of Ala. 1975, Sections 34-14C-1, et. seq.

(3) Consumer or Patient means any person who uses home medical equipment in his or her place of residence.

(4) Home Medical Equipment (HME) means medical devices usable in a residential setting. Home Medical Equipment is any equipment that provides therapeutic benefits or enables the consumer to perform certain tasks that he or she is unable to undertake otherwise due to certain medical conditions and/or illnesses. Home Medical Equipment is considered to be equipment that can withstand repeated use and is primarily and customarily used to serve a medical purpose. Home Medical Equipment includes, but is not limited to:

(a) equipment such as wheelchairs and power-operated vehicles (“scooters”), wheelchair cushions and seating systems, hospital beds, traction equipment, canes, crutches, walkers; respiratory care equipment, including positive air pressure devices, invasive and non invasive ventilators, apnea monitors, aerosol compressors generators, nebulizers, ~~such machines and~~ oxygen therapy equipment, and other such devices; and other medically needed items.

(b) any product intended for use in the home and defined as a medical device by the U. S. Food and Drug Administration under the federal Food, Drug and Cosmetic Act, Chapter 11, Sec. 201. [312](b) and Chapter V, Subchapters (A) and (B).

(c) any product, intended for use in the home, which is a device, instrument, apparatus, machine, or other similar article whose label bears the statement: “Caution: Federal law requires dispensing by or on the order of a physician.”

(d) any product eligible to be reimbursed under the Healthcare Common Procedure Coding System (HCPCS) code listing by any insurance provider, to include, but not limited to, Medicare Program Part B Durable Medical Equipment benefits or Alabama Medicaid Program Durable Medical Equipment benefits.

(e) Home Medical Equipment does not include prosthetics, splints, braces or aids custom fabricated by a licensed health care provider.

(f) Home Medical Equipment does not include vehicle platform lifts or residential platform lifts and stairways chair lifts.

(5) Home Medical Equipment Services means the advertisement, in any form or through any medium, sale, rental, delivery, installation, maintenance, replacement of, or instruction in the use of medical equipment and related supplies used by a sick or disabled individual to obtain care or treatment and be maintained in a residential setting.
~~The advertisement of such services, in any form or through any medium, also constitutes the provision of Home Medical Equipment Services for purposes of these Rules.~~

(6) Home Medical Equipment Services Provider means a corporation, other business entity, or person engaged in the business of providing home medical equipment, either directly or through a contractual arrangement, to an unrelated sick or disabled individual in the residence of that individual.

(7) Licensee means the person or entity to which a license is issued by the Board.

(8) Mail order company means a company which lists its products for consumers to buy, rent or lease via telephone, mailed check with order form, or Internet order and delivers such products directly to the consumer via a postal service, such as the U.S. Postal Service (USPS), UPS, FedEx or another courier service; provided, however, that a company that supplies respiratory care and oxygen equipment, as defined under Rule 473-X-1-.01(4)(a), to Alabama consumers in this manner, or any other home medical equipment necessary to avert an immediate threat to a consumer's health or safety, without which a consumer might be required to seek emergency medical treatment, shall not be considered to be a mail order company for purposes of this rule. Mail order companies do not have a licensed physical location in the state and must comply with the regulations of the Federal Trade Commission (FTC), 16 C.F.R. §§ 435.1 to 435.3, and the USPS. Home Medical Equipment Services Providers whose employees, agents or subcontractors enter the consumer's residence to service home medical equipment supplied by a mail order company or to instruct consumers in the use of such equipment shall not be considered mail order companies.

(89) Person in Charge means any individual, partnership, corporation, association, governmental subdivision or public or private organization that directly or indirectly manages, controls, or oversees the operation of a corporation or other business entity that is a licensee, regardless if that person is a partner, shareholder, owner, officer, director, agent, or employee of the entity.

(910) Change in Ownership or Change in Control means the purchase of either the assets or stock of a Home Medical Equipment Services Provider's Business.

(a) an asset purchase is the purchase of the assets of a business only. The buyer will be operating the business under a new tax identification number (TIN).

(b) a stock purchase is the purchase of all the assets and liabilities of a business, where the buyer will retain and operate the business under its existing TIN.

(4011) Warehouse means a support facility to a licensed location that houses a licensee's surplus inventory of home

medical equipment. A warehouse is not open to the public, may not sell or distribute home medical equipment directly to the consumer and may not be advertised as a licensed location. A warehouse does not meet the supplier standards set forth in 473-X-4-.01 and may not be licensed as a separate location.

HISTORY:

New Rule: Filed July 20, 2001; effective August 24, 2001. **Amended:** Filed July 10, 2006; effective August 14, 2006. **Amended:** Filed February 27, 2009; effective April 3, 2009. **Amended:** Filed October 6, 2009; effective November 10, 2009. **Amended:** Filed July 9, 2013; effective August 13, 2013. **Amended:** Filed January 13, 2014; effective February 17, 2014.