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### 473-X-1 Definitions

#### 473-X-1-.01 Definitions.

(1) <u>Applicant</u> 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) <u>Board</u> means the Board of Home Medical Equipment Services Providers as established by the Code of Alabama, 1975, Sections 34-14C-1, et. seq.

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

(4) <u>Home Medical Equipment</u> (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 scooters, wheelchair cushions and seating systems, breast prostheses, mastectomy bras, hospital beds, traction equipment, canes, crutches, walkers; respiratory care equipment, including invasive and non invasive ventilators, apnea monitors, aerosol generators, nebulizers, such machines and oxygen equipment; 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.

(5) <u>Home Medical Equipment Services</u> means the 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) <u>Home Medical Equipment Services Provider</u> 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) <u>Licensee</u> means the person or entity to which a license is issued by the Board.

(8) <u>Person in Charge</u> 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.

(9) 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.

Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8 Amended: Filed August 17, 2009; Effective Date: October 6, 2009

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### 473-X-2 Employees; Oath; Meeting; Powers.

#### 473-X-2-.01 Employees; Oath; Meeting; Powers.

- (1) The Board may employ an executive director, attorney, experts, and other employees as it may from time to time find necessary, for the proper performance of its duties, and for whom necessary funds are appropriated.
- (2) Before entering public duties of the office, the members of the board shall take the constitutional oath of office.
- (3) The Board shall elect, at the first meeting following October 1<sup>st</sup> each year, a Chair and a Vice Chair. The board shall hold at least two meetings each year. Additional meetings may be held at the discretion of the Chair or upon the written request of any three members of the board. Five members of the board shall constitute a quorum.
- (4) The board shall inspect and pass on the qualifications of applicants and shall issue a license to each successful applicant.
- (5) The board may authorize expenditures as necessary to carry out its duties from the fees that it collects, pursuant to a budget developed and adopted by the board and appropriated by the legislature. In no event shall the expenditures exceed the revenues of the board during any fiscal year.
- (6) The Board may reimburse Board Members for attorney fees incurred if individual members of the Board are personally sued under the Open Meetings Act.

Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8, Act #2000-739, HB 419 of the 2000 Regular Session. Effective Date: July 14, 2010

### 473-X-3 Administrative Procedure.

#### 473-X-3-.01 Administrative Procedure.

- (1) Any person may be heard by the Board in person or through an attorney, as long as they file a written request with the office of the board. The Board will schedule the appearance at the next regular scheduled meeting, provided the request is received at least 14 days prior; otherwise, the appearance will be scheduled for the second meeting following receipt of the request.
- (2) Board meetings shall be conducted following a written agenda, which is provided to each member at least ten days prior to each meeting. The Alabama Open Meetings Act\_and/or Robert's Rules of Order, short form, shall be used as the parliamentary authority for all meetings of the board.
- (3) Upon receipt of an application and the appropriate fee, the fee shall be deposited into the Home Medical Equipment Services Fund in the State Treasury pursuant to Section 34-14C-7.
- (4) If the application is complete and sufficiently meets the standards set by the Board, the office of the board shall schedule an inspection.
- (5) If the application is not complete, the office of the board shall notify the applicant, in writing, of all deficiencies in the application. If the applicant does not return a properly completed application within ninety (90) days of the notification of deficiency, or, if a completed application can not be submitted within ninety (90) days, documentation of the applicant's inability to complete the application process within the specified time period and a request for an extension thereof, the fee is forfeited and the applicant may reapply.
- (6) No one may operate as a Home Medical Equipment Services Provider without a valid license, including during the time a license application is pending.
- (7) The application, the form of which is indexed in the appendix to this section, shall include at a minimum, the following information:
  - (a) Name, physical location, mailing address, and telephone number of the business, including all trade or business names.

- (b) The name of the manager or person in charge of the day-to-day business operations at the physical location.
- (c) The names and home addresses of officers or other persons in positions of control.
- (d) The hours and days of operation of the business.
- (e) A list of categories of equipment and services provided to the public.
- (f) Certification of insurance.
- (g) The Federal Employee identification number assigned to the business. For a sole proprietor this may be the social security number of the owner.
- (h) Disclosure of ownership, which includes: the name of a person, if a person; the full name of a sole proprietor and the name of the business entity, if a sole proprietorship; the name of each partner and the name of the partnership, if a partnership; the name and title of each corporate officer and director, a list of shareholders, the corporate name and the state of incorporation and the name of any parent company, if a corporation; or the full name and title of each member and each manager of a limited liability company, the name of the state where organized and the name of the parent company.
- (i) Certification, signed by a person with the authority to bind the applicant and notarized under oath, indicating that the applicant complies with the rules and regulations of the board, and has truthfully and completely disclosed all ownership and control of the applicant, and that all information submitted on or with the application is true and complete.
- (j) No question should be left blank. If an item does not apply then the applicant should mark the question in a fashion adequate to allow the board to determine that the applicant did not over look it.

(8) Any change in the name, address, control, ownership, manager or Person in Charge of a licensee shall be reported to the office of the board within thirty (30)

days of such change. The change should be reported on the applicable form(s) indexed in the appendices to these rules.

(a)A change only in the physical address of a licensee requires submission of the Application for a Change of Address and the required fee within thirty (30) days of such change, and a site inspection of the new facility.

(b) A change only in the Person in Charge of a licensee requires submission of the Application for Change of Person in Charge within thirty (30) days of such change.

(c) A change only in the ownership or control of a licensee requires submission of the Application for Change in Ownership within (30) days of such change.

1. The purchase of only the assets of a business (an "asset purchase") requires the buyer to operate the business under a new tax identification number (TIN). A change in the TIN requires the new owner to obtain a new Medicare supplier number and complete the Application for Change in Ownership or Control and a new application for licensure with the board. The new owners must successfully complete the reapplication process before a new license can be issued.

2. The purchase of all the assets and liabilities of a business (a "stock purchase") permits the buyer to retain and operate the business under the existing TIN. The new owner must submit only an Application for Change in Ownership or Control.

(d) If more than one change occurs simultaneously in the information reflected on the licensee's application, including but not limited to, the physical address, equipment provided, FEIN or SSN, or if disciplinary actions against the licensee have ensued before this board or in any other licensing state or jurisdiction, the licensee must complete and submit a new application for licensure reflecting all such changes within thirty (30) days of such change and successfully complete the reapplication process before a new license can be issued.

(9) Certain entities are exempt pursuant to §34-14C-5 Code of Alabama, 1975.

**Author:** The Alabama Board of Home Medical Equipment Services Providers **Statutory Authority:** <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8

#### 473-X-4 Inspection Standards.

#### 473-X-4-.01 Inspection Standards.

- (1 The Board hereby incorporates the Centers for Medicare and Medicaid Services (CMS) Medicare Durable Medical Equipment Provider of Service (DMEPOS) Supplier Standards as additional requirements with which all applicants must comply for licensure; provided however the Board does not incorporate the requirement for accreditation as additional requirements with which applicants for licensure must comply.
- (2) A Home Medical Equipment Services Provider shall maintain a physical facility on an appropriate site. The facility must contain space for storing business records, including the supplier's delivery, maintenance, and patient records. For purposes of this rule, a residence, post office box or commercial mailbox is not considered a physical facility
- (3) A Home Medical Equipment Services Provider must maintain a primary business telephone at the physical facility. This telephone number must be listed under the name of the business and in the business section of the local telephone company directory. The exclusive use of a pager number, call forwarding, answering service, cell phone, or answering machine may not be used as the primary business telephone.
- (4) The physical facility must be staffed during normal business hours, and must have a visible sign with the name of the business, business hours, and the phone number required by.
- (5) Medical equipment shall be maintained in a clean and sanitary condition and stored in a dry, well-ventilated area. Routine maintenance, preventative maintenance, and repairs shall be performed according to manufacturer's guidelines. The home medical equipment services provider shall provide consumer instruction regarding the use of home medical equipment requiring services. Out of State providers shall also provide sufficient contact information in writing, including, but not limited to, a toll-free telephone number, physical address and hours of operation, meeting the requirements of paragraphs (3) and (4) above, to all consumers may obtain repairs,

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supplies and other services required to maintain or use the home medical equipment. Delivery services include transportation of equipment to and from consumer, equipment setup, and record keeping.

- (6) Records shall be maintained to the same extent as required by federal regulations that include: any physician orders, certificates of medical necessity, signed and dated delivery slips, documentation of all services, equipment, and maintenance received, and other information as appropriate for the equipment provided.
- (7) Out of State applicants are required to pay for non-refundable travel expenses directly incurred by an inspection in addition to the inspection fee prior to an inspection being scheduled.
- (8) Applicants who have passed the site inspection will have (60) days from the date of written notification of approval to submit the license fee or the application and fees will be forfeited.
- (9) Licensees who fail to pass an inspection upon the issuance of a complaint, for cause, upon an application for license renewal or for any other cause must cease and desist their operations upon receipt of written notice of failure to pass inspection until they have come into compliance with all applicable standards, unless the Board negotiates a plan for compliance with the licensee and conducts a further inspection for compliance at a time to be determined by the Board. The licensee will be required to remit an additional re-inspection fee to cover the board's expenses in conducting the re-inspection to determine compliance.

Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8 Amended: Filed August 17, 2009; Effective Date: October 6, 2009

#### 473-X-5 Ethics

#### 473-X-5-.01 Ethics.

 The board hereby incorporates by reference the Medicare Supplier Standards [found at 42 C. F. R. pt. 424, sec 424.57 (c), effective December 11, 2000]; with the exception of accreditation standards.

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Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8, Act #2000-739, HB 419 of the 2000 Regular Session. Effective Date: July 17, 2008

#### 473-X-6 Denial, Revocation, Suspension.

#### 473-X-6-.01 Denial, Revocation, Suspension.

- (1) The board may refuse to grant an initial or renewal license if any of the following are found to apply to the applicant, as defined herein:
  - (a) Conviction of a crime that the board determines to be of a nature as to render a person unfit to hold a license.
  - (b) Violation of ethical standards promulgated by the board.
  - (c) Fraud or misrepresentation.
  - (d) Other just and sufficient cause, such as, but not limited to the following:

1. Violation of rules, regulations, and standards set forth by the board.

2. Making misleading, deceptive, untrue, or fraudulent representations.

3. Engaging in business practices harmful or detrimental to the public.

4. Conviction of a felony.

5. Willful or repeated violations of the Rules and Regulations of the Alabama Board of Home Medical Equipment Services Providers.

6. Falsifying records.

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7. Failure to report a change of name, address, control, ownership or person in charge within 30 days.

8. Failure to cooperate with an inspection or with an investigation conducted by the board.

(2) Any person may file a complaint with the board regarding the failure to obtain a license for the provisioning of home medical equipment services as required by this board. Complaints shall be in a form prescribed by the board and shall be verified under oath by the complainant. If the board determines that the complaint is substantive and relevant, it may inspect the operations of the provider to determine compliance with the rules and regulations established by the board. Upon receipt of the inspection report the board may either:

- (a) dismiss the complaint, or
- (b) send notice of non-compliance to the licensee and authorize representatives of the board to negotiate a plan of compliance with the licensee, which may include the negotiation of a written settlement, consent order or default on terms that are mutually agreeable to the parties, which terms may include the assessment of fines or fees to be paid to the board.

Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8 Effective Date: July 10, 2006

### 473-X-7-.01 Appeal to the Board.

(1) Any entity or person against whom an administrative fine has been levied by the board for providing home medical equipment services without a license as required under Section 34-14C-4, Code of Alabama, 1975, or who has been administratively enjoined from providing home medical equipment services without such a license, shall be entitled to pursue an appeal through the board for reconsideration of such decisions rendered after a contested case proceeding. This rule shall also govern appeals of inspection results from any entity or person to whom a written notice of failure to pass inspection has been issued by the board.

- (2) The board shall entertain written requests for reconsideration of inspection results or of its decision in a contested case proceeding in an appeal hearing by either party thereto if timely submitted within thirty (30) days from the rendition of said decision in a written final order adopted by the board.
- (3) The request should be based upon newly discovered evidence which would justify relief from the decision rendered.
- (4) Such requests should include, by written memorandum or brief, the detailed basis for such reconsideration. The opposing party shall have the opportunity to present a written reply memorandum or brief challenging such basis within thirty (30) days from the submission of the request for reconsideration.
- (5) The board shall review the written arguments of the parties at its next regular or special meeting and, based upon such review, determine in its discretion by a majority vote of a quorum of its members whether to sustain its previous decision or grant such relief from the decision as may be appropriate. In reviewing the request, the board may, at its sole discretion, hear further oral argument or new sworn testimony or suggest supplemental responses. The board shall render a written order setting forth the determination of the board within thirty (30) days of the vote reflecting the determination of the board.
- (6) The filing of the request for reconsideration shall be at the option of the parties and should not be deemed as a prerequisite to, or hindrance of, either party's right to judicial review of a board decision in accordance with the procedures provided under the Alabama Administrative Procedure Act, Chapter 22, Title 41, Code of Alabama, 1975.

Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: Section 34-14C-6(c), <u>Code of Alabama, 1975</u> Effective Date: July 10, 2006

#### 473-X-8-.01 Renewal of License.

(1) The Home Medical Equipment Service Provider license shall be valid for one (1) year, expiring on August 31<sup>st</sup> of each year; however, the initial licensure period for any given license may be prorated so that its expiration date coincides with the August 31<sup>st</sup> renewal date for all valid licenses. The license fee will not be prorated for abbreviated licenses issued.

(2) Failure to renew within sixty (60) days after the expiration date of the current license will result in an expired license. Home Medical Equipment Services Providers will not be permitted to provide home medical equipment services with an expired license. Licensees who operate under expired licenses shall be subject to the penalties established under Section 34-14-C-6(a), Code of Alabama, 1975.

(3) One (1) renewal notice will be provided by U.S. Mail to the licensee's last address of record sixty (60) days prior to the renewal date. Licensees are responsible to maintain a current mailing address with the Board. One final renewal notice will be placed by an automated calling service on August 21<sup>st</sup> to licensees who have not renewed by this date.

(4) To be eligible for renewal, an applicant shall:

(a) Hold a valid, active Alabama license; and

(b) Timely submit a completed and signed renewal application and required fee(s) to the Board.

(5) Renewals will be submitted online via the Board's web site. Licensees may request manual renewal by making a written request to the Board office.

(6) Failure to receive the renewal application or notice of renewal shall not relieve the licensee of the responsibility to renew the license by the expiration date.

(7) Once a license has expired, a cease and desist letter will be issued by certified mail to the last address of record and a new application and inspection will be required for licensure.

(8) The Board may notify third party payors, regulatory boards and agencies, and governmental agencies responsible for reimbursement to home medical equipment services providers such as Medicaid and Medicare, of expired licenses no earlier than November 1<sup>st</sup> of each licensing year.

Author: The Alabama Board of Home Medical Equipment Services Providers Statutory Authority: Section 34-14C-6(c), Code of Alabama, 1975 Effective Date: May 6, 2008

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### APPENDICES 1 - Fees.

- \$250 License/Renewal Fee (per location)
- \$500 Initial Inspection Fee (per location)
- \$150 Re-Inspection Fee
- \$275 Site Inspection Fee upon Change of Physical Location

Author: Alabama Board of Home Medical Equipment Services Providers Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8, Act #2000-739, HB 419 of the 2000 Regular Session. Effective Date: May 6, 2008

#### **APPENDICES 2** - Forms associated with these Rules and Regulations.

Application for Initial License

Application for License Renewal

Application for change in address, control, or person in charge

Consumer complaint

Request for Hearing or Inclusion on Agenda

Site Inspection Form

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Author: Larry Ready Statutory Authority: <u>Code of Alabama, 1975</u> §34-14C1 thru §34-14C8, Act #2000-739, HB 419 of the 2000 Regular Session. Effective Date: May 25, 2001

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