RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-29
STANDARDS FOR HOME CARE ORGANIZATIONS PROVIDING HOME MEDICAL EQUIPMENT

TABLE OF CONTENTS

1200-08-29-.01 DEFINITIONS.

(1) Abuse. The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.

(2) Administrator. A person who:

(a) Is a licensed physician with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(b) Is a registered nurse with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(c) Has training and experience in health service administration and at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs.

(3) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(4) Agency. A Home Care Organization providing home medical equipment.

(5) Assistive Technology Practitioner (ATP). Service providers primarily involved in evaluating the consumer's needs and training in the use of a prescribed wheeled mobility device.

(6) Assistive Technology Supplier (ATS). Service providers involved in the sale and service of commercially available wheeled mobility devices.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-29-.01, continued)

(9) Clinical Note. A written and dated notation containing a patient assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the patient.

(10) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(11) Competent. For the purpose of this chapter only, a patient who has decision-making capacity.

(12) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(13) Department. The Tennessee Department of Health.

(14) Do-Not-Resuscitate Order (DNR). A written order, other than a POST, not to resuscitate a patient in cardiac or respiratory arrest in accordance with accepted medical practices.

(15) Evaluation. The determination and documentation of the physiological and functional factors that impact the selection of an appropriate seating and wheeled mobility device.

(16) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(17) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(18) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed legal guardian or conservator with health care decision-making authority, or the patient's surrogate as determined pursuant to Rule 1200-08-29-.13 or T.C.A. §33-3-220.

(19) Home Care Organization. As defined by T.C.A. § 68-11-201, a "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(20) Home Medical Equipment.

(a) Medical equipment intended for use by the consumer including, but not limited to the following:

(Rule 1200-08-29-.01, continued)

1. 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.”;

2. Ambulating assistance equipment;

3. Mobility equipment;

4. Rehabilitation seating;

5. Oxygen care equipment and oxygen delivery systems;

6. Respiratory care equipment and respiratory disease management devices.

7. Rehabilitation environmental control equipment;

8. Ventilators;

9. Apnea monitors;

10. Diagnostic equipment;

11. Feeding pumps;

12. A bed prescribed by a physician to treat or alleviate a medical condition;

13. Transcutaneous electrical nerve stimulator;

14. Sequential compression devices; and

15. Neonatal home phototherapy devices.

(b) Home medical equipment does not include:

1. Medical equipment used or dispensed in the normal course of treating patients by hospitals and nursing facilities as defied in this part, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical equipment to an individual’s residence;

2. Upper and lower extremity prosthetics and related orthotics;

3. Canes, crutches, walkers, and bathtub grab bars;

4. Medical equipment provided through a physician’s office incident to a physician’s service;

5. Equipment provided by a pharmacist which is used to administer drugs or medicine that can be dispensed only by a pharmacist; or

6. Enteral and parenteral equipment provided by a pharmacist.

(21) Home medical equipment provider. Any person who provides home medical equipment services.

(Rule 1200-08-29-.01, continued)

(22) Home medical equipment services. A service provided by any person who sells or rents home medical equipment for delivery to the consumer' place of residence in this state, regardless of the location of the home medical equipment provider.

(23) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(24) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(25) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(26) Legal Conservator. Any person authorized to act for the patient pursuant to any provision of T.C.A. Title 34, Chapters 5 and 11 through 13.

(27) Legal Guardian. Any person authorized to act for the resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(28) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(29) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(30) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(31) Medical Record. Information that pertains to confinement or services rendered to patients, including one or more of the following:

(a) medical histories;

(b) records;

(c) reports;

(d) clinical notes;

(e) summaries; or

(f) orders.

If the patient does not require any clinical services from the home medical equipment company, the medical record will consist of the physician order only.

(Rule 1200-08-29-.01, continued)

(32) Medical Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(33) Misappropriation of Patient/Resident Property. The deliberate misplacement, exploitation or wrongful, temporary or permanent use of an individual's belongings or money without the individual's consent.

(34) Neglect. The failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of the living will, shall not be deemed "neglect" for purposes of these rules.

(35) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(36) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed by the Tennessee Board of Osteopathic Examination. For the purpose of this chapter only, a physician who is licensed to practice medicine or osteopathy in a state contiguous to Tennessee, who have previously provided treatment to the patient and has an ongoing physician-patient relationship with the patient for whom a referral is to be made, may refer a patient residing in this state to a home care organization providing hospice services duly licensed under this chapter. This shall not be construed as authorizing an unlicensed physician to practice medicine in violation of T.C.A. §§ 63-6-201 or 63-9-104.

(37) Physician Assistant. A person who has graduated from a physician assistant educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a physician assistant under title 63, chapter 19.

(38) Qualified Rehabilitation Professional. A health care professional with in the professional's scope of practice licensed under Title 63; or an individual who has appropriately obtained the designation of ATS or ATP, meeting all requirements thereof, as established by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA).

(39) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(40) Shall or Must. Compliance is mandatory.

(41) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(42) Surrogate. The patient's conservator, or if none, a competent adult most likely to know the wishes of the patient with respect to the possible withholding of resuscitative services or withdrawal of resuscitative services.

(Rule 1200-08-29-.01, continued)

(43) Wheeled Mobility Device. A wheelchair or wheelchair and seated positioning system prescribed by a physician and required for use by the patient for a period of six (6) months or more. The following Medicare wheelchairs base codes are exempt: K0001, K0002, K0003, K0004, K0006, and K0007 as long as the consumer weighs less than three hundred (300) pounds.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-226, 68-11-268, and 68-11-303.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendments filed December 23, 2009; effective March 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-29-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the home care organization providing home medical equipment shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing home medical equipment.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Department.

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules.

(d) The applicant must prove the ability to meet the financial needs of the agency.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid an inspection and review process.

(f) The applicant shall allow the home care organization providing home medical equipment to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(Rule 1200-08-29-.02, continued)

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

(a) For the purpose of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to, the following:

1. Transfer of the agency's legal title;

2. Lease of the agency's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;

6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate agency owner with one or more corporations; or

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or

5. Corporate stock transfer or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the

(Rule 1200-08-29-.02, continued)

ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each home care organization providing home medical equipment shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;

2. the license fee provided in rule 1200-08-29-.02(2)(b); and

3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-29-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act by the agency;

(Rule 1200-08-29-.03, continued)

(d) Conduct or practices found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or

(e) Failure to renew the license.

(2) The Board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patient in the agency.

(c) The conduct of the agency in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the agency of statutes, rules or orders of the Board.

(3) When an agency is found by the Department to have committed a violation of this chapter, the Department will issue to the agency a statement of deficiencies. Within ten (10) days of receipt of the statement of deficiencies the agency must return a plan of correction indicating the following:

(a) How the deficiency will be corrected; and

(b) The date upon which each deficiency will be corrected;

(4) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, and 68-11-206 through 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed March 1, 2007; effective May 15, 2007.*

1200-08-29-.04 ADMINISTRATION.

(1) Governing Body. The licensee shall assume full legal authority and responsibility for the operation of the agency. The governing body shall appoint a qualified administrator, arrange for professional advice, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the agency. The name and address of each officer, director, and owner shall be disclosed. If the agency is a corporation, all ownership interests of five (5) percent or more (direct or indirect) shall also be disclosed.

(2) Administrator. The administrator shall organize and direct the agency's ongoing functions; maintain ongoing communication between and among the governing body, the professional personnel and the staff; employ qualified personnel, ensure adequate staff education and evaluation for all personnel involved in direct care of the patient; ensure the accuracy of public information materials and activities; and implement an effective accounting system. A person with sufficient experience and training shall be authorized in writing to assume temporary duty during the administrator’s short-term absence. Any change of administrators shall be reported to the Department within fifteen (15) days.

(Rule 1200-08-29-.04, continued)

(3) An administrator shall serve no more than one (1) licensed home care organization unless that home care organization provides other categories of home care organization services under the same ownership and at the same location.

(4) Organization Structure. The agency's structure is such that responsibility and accountability for the program are clearly defined. An organizational chart (A) shows the relationship of the administrator to the governing body; (B) clearly identifies lines of supervision; and (C) accurately defines the chain of command for in-home personnel.

(5) Accreditation. Any home medical equipment provider accredited by the Joint Commission on Accreditation of Health Care Organizations, Community Health Accreditation Program or other approved accrediting bodies may submit documents evidencing current accreditation and shall be presumed to comply with the requirements of the Board. Licensing of a home medical equipment provider which has been accredited by the Joint Commission on Accreditation of Health Care Organizations, Community Health Accreditation Program or other approved accrediting bodies shall become effective upon written notification from the Board's staff that the accreditation meets the standards set out in the rules and regulations promulgated pursuant to T.C.A. §§ 68-11-201, et seq.

(6) Personnel. Employees shall be qualified for the positions they hold and meet the education, training, and experience requirements defined by the agency.

(a) All employees shall receive and participate in an orientation program prior to assuming patient care responsibilities. The agency's written orientation plan shall outline topics to be covered; attendance requirements; method to verify topics discussed; a description of the orientation process; and the orientation plan shall include, but is not limited to:

1. Review of the individual's job description and duties to be performed;

2. Organizational chart;

3. Supervision;

4. Recordkeeping and reporting;

5. Confidentiality;

6. Patient's rights and responsibilities;

7. Pertinent personnel policies; and

8. Skills validation, as applicable.

(b) The agency shall maintain a personnel file for each employee which contains the following information:

1. A completed application;

2. References;

3. Work experience;

4. Educational preparation;

(Rule 1200-08-29-.04, continued)

5. Job description which lists the minimum education, training, and experience requirement; job responsibilities; and title of immediate supervisor;

6. Annual performance appraisal or individual evaluations on specific job descriptions which include demonstrated current competency and proof that performance appraisal results were shared with employee;

7. Prior training;

8. Proof of orientation; and

9. Evidence of current license, if applicable.

(c) Medical equipment delivery technicians who deliver and install respiratory equipment shall be determined to be competent by their employer prior to independently delivering and setting up the respiratory equipment in a patient's home. The home medical equipment supplier must maintain documentation to demonstrate that competency requirements are met. Standard competencies will include at a minimum the following:

1. Role responsibilities;

2. Cylinders;

3. Pressure regulators/Flow controllers;

4. Home liquid oxygen systems;

5. Oxygen concentrators;

6. Oxygen analyzers;

7. Humidifiers;

8. Low flow nasal cannula; and

9. Small volume medication nebulizers with air compressors.

(d) Medical equipment delivery technicians shall be determined by their employer to be competent in their understanding of which acts they may and may not perform.

(e) The Board may in its discretion, after consultation with the Tennessee Association for Home Care and the Tennessee Society for Respiratory Care, encourage the use of certain competency documents developed by these two organizations to ensure compliance with the provisions of (c) and (d).

(7) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

(a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

(Rule 1200-08-29-.04, continued)

(c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

(8) "No smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.

(9) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-1-222, 68-11-226, 68-11-268, and 71-6-121.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-29-.05 ADMISSIONS, DISCHARGE AND TRANSFERS.

(1) The agency only admits patients whose needs can be met by the services the agency provides.

(a) There shall be written policies and procedures and an organizational process that indicates employees with the necessary skill and training are assigned to assess the level and type of care/service required by patients referred to the agency, and to determine whether the patient is eligible for admission based on the agency's criteria and availability of services to meet the patient's needs. There shall also be a reasonable time frame in which the patient's eligibility for admission is assessed which takes into account the patient's service needs.

(b) There shall be a written policy that addresses the agency's compliance with federal, state, and local anti-discrimination laws in the selection of patients.

(2) Patients shall be transferred or referred to other organizations/agencies in the community when service needs are identified by staff or patients which cannot be met by the agency.

(3) The agency shall ensure that no person, on the grounds of race, color, national origin or handicap, will be excluded from participation in, be denied benefits of, or otherwise be subjected to discrimination in the provision of any care or service of the agency. The agency shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed June 25, 2007; effective September 8, 2007.*

1200-08-29-.06 BASIC AGENCY FUNCTIONS.

(1) Patient Instruction. The agency shall have written guidelines relating to patient and/or caregiver training and education that includes at a minimum:

(Rule 1200-08-29-.06, continued)

(a) Financial responsibilities;

(b) Equipment use and maintenance;

(c) Patient rights and responsibilities;

(d) Emergency/back-up systems and trouble shooting procedures, if applicable; and

(e) How to contact the agency during regular business hours and after hours, if applicable.

(2) Infection Control. The agency shall have written policies and procedures relating to infection control. Employees shall consistently follow infection control procedures in the provision of care to the agency's patients. The written policies and procedures at a minimum must address standards and education of staff about:

(a) Infection control measures;

(b) Handwashing;

(c) Use of universal precautions and personal protective equipment;

(d) Appropriate cleaning and disinfection of reusable equipment and supplies; and,

(e) Disposal of regulated waste.

(f) A Home Care Organization Providing Home Medical Equipment shall have an annual influenza vaccination program which shall include at least:

1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Home Medical Equipment will encourage all staff and independent practitioners to obtain an influenza vaccination;

2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at http://tennessee.gov/health/topic/hcf-provider);

3. Education of all employees about the following:

(i) Flu vaccination,

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza;

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner’s designee.

(Rule 1200-08-29-.06, continued)

(3) In-Home Safety. The agency shall educate staff, patients, and caregivers about basic home safety related to the use of equipment delivered to the home. There shall be a procedure for reporting and documenting all incidents. There shall be an incident report form and identification of the types of situations that should be reported and documented.

(4) Equipment Management.

(a) Client-ready equipment shall be durable in nature, sanitized, and in proper working order. The agencyzation shall have clearly defined guidelines for the cleaning, storage, and transportation of client-ready equipment. These guidelines shall include, but are not limited to:

1. Separation of clean and unclean equipment;

2. Appropriate warehousing and tagging of equipment;

3. Use of appropriate cleaning agents, as directed by the manufacturer;

4. Routine maintenance of equipment; and

5. Separation of inoperative equipment.

(b) Agency employees shall be qualified to deliver, perform environmental assessments, set up, and demonstrate safe and proper use of all home medical equipment according to manufacturer's guidelines.

(c) Agency guidelines shall clearly define training, qualifications, and skills validation required by employees to perform routine maintenance and repairs of all home medical equipment. Routine maintenance, preventive maintenance, and repairs shall be performed according to manufacturer's guidelines. Agency employees shall only perform repair services within their respective areas of documented training and expertise. There shall be guidelines that define appropriate use of outside repair sources.

(d) The agency shall have written guidelines for accurate performance quality tracking of equipment in compliance with the FDA's Medical Device Tracking program and facilitate any recall notices sent by the manufacturer. These guidelines shall address the:

1. Immediate removal from equipment inventory;

2. Notification to the client; and

3. Exchange of equipment in the field.

(e) Disposition of recalled inventory shall be handled according to manufacturer's guidelines.

(f) Only durable medical equipment shall be returned to the company for processing. The agency shall have written policies and procedures for processing contaminated or soiled durable medical equipment and shall be in compliance with universal precautions. Guidelines shall specify the separation of dirty equipment from client ready equipment in the warehouse and delivery vehicles.

(5) Physical Location. Each parent and/or branch shall:

(Rule 1200-08-29-.06, continued)

(a) Be located in Tennessee;

(b) Be staffed during normal business hours and have a working telephone;

(c) Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;

(d) Meet all local zoning requirements; and

(e) Have all required current licenses and/or permits conspicuously posted in the agency.

(6) Additional Compliance Requirements. The agency shall comply with all federal, state, and local laws and regulations.

(a) Written policies and procedures shall be established and implemented by the agency regarding compliance with all applicable federal, state, and local laws and regulations.

(b) An agency providing prescribed wheeled mobility devices shall obtain a complete face-to-face written evaluation and recommendation by a qualified rehabilitation professional for consumers of prescribed wheeled mobility devices.

(c) The agency must have on staff, or contract with, a qualified rehabilitation professional.

(d) As of July 1, 2007, a one hundred eighty (180) day grace period shall be provided to agencies that provide prescribed wheeled mobility devices if the qualified rehabilitation professional on staff ceases to be employed and the agency has no other qualified rehabilitation professional on staff.

(e) All agencies making available prescribed wheeled mobility devices to consumers in Tennessee shall have a repair service department or a contract with a repair service department located in the state. The agency shall have a qualified technician with knowledge and capability of servicing the product provided to the consumer. As used in this section, “consumer” means an individual for whom a wheeled mobility device, manual or powered, has been prescribed by a physician, and required for use for a period of six (6) months or more.

(f) Delivery and final fitting of a wheeled mobility device shall be determined by a qualified rehabilitation professional. Exempt are wheeled mobility devices under category Group 1 Medicare codes.

(g) The agency shall comply with the following supplier standards:

1. Fill orders from its own inventory or inventory of other companies with which it has contracts to fill such orders, or fabricates or fits items for sale from supplies it buys under a contract;

2. Oversee delivery of items that the supplier ordered for the patient. The supplier is also responsible to assure delivery of large items to the patient;

3. Honor all warranties, express or implied, under applicable state law;

4. Answer questions or complaints about an item or use of an item that is sold or rented to the patient. If the patient has questions, the supplier will refer the patient to the appropriate carrier;

(Rule 1200-08-29-.06, continued)

5. Maintain and repair directly, or through a service contract with another company, items it rents to a patient;

6. Accept returns for substantial medical equipment;

7. Provide the following disclosure information to the department:

   (i) The identity of each person having a five percent (5%) or more ownership or controlling interest in the agency.

   (ii) The identity of subcontractors in which the agency has a five percent (5%) or more ownership interest;

   (iii) At the time such information is disclosed or at any time during the three (3) year period preceding the date such information is supplied, managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any other entity providing items or services that receives payment under title XVIII; and

   (iv) Managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any penalties, assessments, or exclusions assessed against such person under Section 1128, 1128A, or 1128B of the Social Security Act;

8. Maintain general and product liability insurance; and

9. Disclose consumer information to each patient. This consists of a copy of the supplies standards to which it must conform.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-206, 68-11-209, 68-11-226, and 68-11-304.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed October 11, 2007; effective December 25, 2007. Amendment filed December 23, 2009; effective March 16, 2010. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed July 18, 2016; effective October 16, 2016.*

1200-08-29-.07 RESERVED.

1200-08-29-.08 RESERVED.

1200-08-29-.09 RESERVED.

1200-08-29-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(Rule 1200-08-29-.10, continued)

(a) Waste human blood and blood products such as serum, plasma, and other blood components;

(b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care; and

(c) Other waste determined to be infectious by the agency in its written policy.

(3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.

(b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents, and does not create a nuisance.

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-08-29-.11 RECORDS AND REPORTS.

(1) The home care organization providing home medical equipment shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(Rule 1200-08-29-.11, continued)

(2) The home care organization providing home medical equipment shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the home care organization providing home medical equipment or to the health and safety of its patients and personnel; and

(d) Fires at the home care organization providing home medical equipment that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(3) Patient Records shall be maintained for each patient who receives in-home services. The patient record must contain detailed, accurate documentation that reflects all of the services or care provided, directly or by contract. The patient record shall contain at a minimum the following:

(a) Documentation of patient education and instruction;

(b) Physician orders as required;

1. A home care organization providing home medical equipment is authorized to receive and appropriately act on a written order for a plan of care for a patient concerning a home health service signed by a physician that is transmitted to the agency by electronically signed electronic mail. Such order that is transmitted by electronic mail shall be deemed to meet any requirement for written documentation imposed by this regulation.

(c) Documentation that patient has been fully informed of patient rights and responsibilities and at a minimum, the right to:

1. Be fully informed in advance about care and treatment to be provided by the agency;

2. Be fully informed in advance of any changes in the care or treatment to be provided by the agency when those changes may affect the patient's well-being;

3. Voice grievances without fear of discrimination or reprisal;

4. Confidentiality of personal information;

5. Have one's property treated with respect; and

6. Be fully informed of the agency’s telephone number for information, questions, and/or complaints about services provided by the agency and a description of the process for investigating and resolving complaints. The agency shall investigate and resolve all patient complaints and document the results in a timely manner. The agency shall label all equipment with the name, address, and telephone number of the agency.

(Rule 1200-08-29-.11, continued)

(4) Patient Confidentiality. The agency shall have written policies dealing with patient information. Patient records shall contain signed release of information statements/forms when the agency bills a third-party payor or shares information with others outside the agency. Patient confidentiality polices will address, at a minimum, the following:

(a) A definition of confidential information;

(b) Persons/positions authorized to release confidential information;

(c) Conditions which warrant release of confidential information;

(d) Persons to whom confidential information may be released;

(e) Policies and procedures for obtaining signatures on, using, and filing release of information forms;

(f) Who has authority to review patient records; and

(g) A statement that training in confidentiality is mandatory for all employees, so that personnel are knowledgeable about and consistently follow confidentiality polices and procedures.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, 68-11-211, and 68-11-260.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed September 1, 2004; effective November 15, 2004. Amendment filed February 23, 2007; effective May 9, 2007. Amendments filed January 3, 2012; effective April 2, 2012.*

1200-08-29-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, and the refusal and its reason must be reported to the treating physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record; and

(e) To have his or her records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The agency must have policies to govern access and duplication of the patient's record.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

(Rule 1200-08-29-.12, continued)

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-08-29-.13 REPEALED.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal filed September 1, 2004; effective November 15, 2004.*

1200-08-29-.14 DISASTER PREPAREDNESS.

(1) All agencies shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The agency shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

(2) All agencies shall establish and maintain a file of documents demonstrating communications and cooperation with the local agency.

(3) Emergency Preparedness Plan. All agencies shall establish procedures for emergency response to provide continued service, 24 hours a day, seven days a week, to the patient base on service interruption for apnea monitors, ventilators, suction pumps and oxygen. The agency shall have written policies and procedures for back-up systems for equipment or power failure for apnea monitors, ventilators, suction pumps and oxygen.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*