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## Rulemaking Hearing Rule(s) Filing Form

*Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).*

*Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).*

**Agency/Board/Commission:** TN Health Facilities Commission, Board for Licensing Health Care Facilities

**Division:** N/A

**Contact Person:** Logan Grant, Executive Director

**Address:** Andrew Jackson Bldg., 9th Fl., 502 Deaderick St., Nashville, TN

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**Revision Type (check all that apply):**

☒ Amendment

☐ New

☐ Repeal

☒ Content based on previous emergency rule filed on 06/26/2023

☒ Content is identical to the emergency rule

**Rule(s)** (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that ALL new rule and repealed rule numbers are listed in the chart below. Please enter only ONE Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0720-30	Standards for Home Care Organizations Providing Home Medical Equipment
Rule Number	Rule Title
0720-30-.01	Definitions
0720-30-.02	Licensing Procedures
0720-30-.03	Disciplinary Procedures
0720-30-.04	Administration
0720-30-.06	Basic Agency Functions
0720-30-.11	Records and Reports

Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <https://sos.tn.gov/products/division-publications/rulemaking-guidelines>.

Chapter Number 0720-30  
Standards for Home Care Organizations  
Providing Home Medical Equipment

Rule 0720-30-.01 Definitions is amended by deleting paragraph (21) and adding new paragraphs (12), (22) and (45), and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraphs shall read:

- (12) **Contact Person.** The individual selected by the agency who will serve as the point-of-contact to communicate with the Health Facilities Commission. The agency must provide a name, title, telephone number, and electronic mail address of the contact person on the appropriate form.
- (22) **Home medical equipment provider.** Any agency which provides home medical equipment services.
  - (a) Providers may fall into the following categories:
    - 1. In-state providers who have a physical location;
    - 2. In-state providers who have no physical location;
    - 3. Out-of-state providers who do not have a physical location; or
    - 4. Mail order companies.
  - (b) Providers who do not have a physical location must comply with survey requirements and provide access and documentation to surveyors necessary to conduct a survey.
  - (c) Designation on whether or not an agency has a physical location shall be located on the agency's wall certificate.
- (45) **Survey material.** Survey material is any material stored in electronic or physical format that may be necessary to conduct a survey. The survey material includes, but is not limited to, personnel files, patient medical records, policies and procedures, data, background checks, abuse registry checks, facility reported incidents, litigation and bankruptcy history, current licensure status, copies of investigations, discipline records in any other state in which the provider is licensed, and video records or files, if available.

Authority: T.C.A. §§ 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.

Rule 0720-30-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (2)(f) and adding new paragraph (1), subparagraphs (2)(f) and (2)(g), and paragraph (5), so that as amended, the new paragraphs and subparagraphs shall read:

- (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) A license shall be issued to the person or persons named and for the premises listed in the application for licensure, if a physical location in Tennessee is listed.
  - (b) The name of the home care organization providing home medical equipment shall not be changed without first notifying the Commission in writing.



- (c) Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance.
- (d) The license shall be conspicuously posted in the home care organization providing home medical equipment, if a physical location in Tennessee is listed.
- (e) If a provider does not desire an in-state location, this information is required to be provided at the time of application.
- (2) In order to make application for a license:
  - (f) The applicant, through the designated contact person, shall allow the home care organization providing home medical equipment to be inspected by a Commission surveyor and provide access to survey material. 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.
  - (g) If a physical location in Tennessee is not desired, the provider shall designate the type of category desired upon initial application.
- (5) Conversion of Designated License Category. If a licensee wishes to convert to a different designated license category under paragraph (22) of Rule 0720-30-.01, a Notice of Intent to Convert must be received by the Commission.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-216, 68-11-226, and Chapter 846 of the Public Acts of 2008, § 1.

Rule 0720-30-.03 Disciplinary Procedures is amended by deleting subparagraphs (1)(d) and (1)(e) and adding new subparagraphs (1)(d), (1)(e) and (1)(f), and paragraph (5), so that the new paragraph and subparagraphs shall read:

- (1) The Board may suspend or revoke a license for:
  - (d) Conduct or practices found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency;
  - (e) Failure to renew the license; and
  - (f) Failure to comply with survey document requests after three (3) written requests to the contact person are made by a surveyor.
- (5) When an agency contact person fails to respond to the third written request for documentation from a surveyor, the agency shall be subject to a civil monetary penalty ranging from five hundred dollars (\$500.00) to five thousand dollars (\$5,000.00), and disciplinary action up to revocation of the license. If the same violation has occurred within the last twelve (12) months, the civil monetary penalty may be doubled.

Authority: T.C.A. §§ 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206 through 68-11-209, and 68-11-226.

Rule 0720-30-.04 Administration is amended by adding new paragraph (10), so that the new paragraph shall read:

- (10) An agency without a physical location in Tennessee shall not be subject to the requirements of 0720-30-.04(7)-(9).

Authority: T.C.A. §§ 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-SS-7039 (November 2022)

226, 68-11-268, and 71-6-121.

Rule 0720-30-.06 Basic Agency Functions is amended by deleting paragraph (5) and substituting the following new language, so that as amended, the new paragraph shall read:

(5) Location.

(a) If a provider chooses to have a physical location in Tennessee, each parent and/or branch shall:

1. Be located in Tennessee;
2. Be staffed during normal business hours and have a working telephone;
3. Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;
4. Meet all local zoning requirements; and
5. Have all required current licenses and/or permits conspicuously posted in the agency.

(b) If an agency chooses not to have a physical location in Tennessee, each parent and/or branch shall:

1. Be licensed in Tennessee;
2. Be staffed during normal business hours and have a working telephone and electronic mail address;
3. Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;
4. Have all required current licenses with appropriate designation and/or permits available for inspection; and
5. Upon initial licensure, provide to the Commission the means and method of entry to a virtual portal for surveyors to access survey material.

Authority: T.C.A. §§ 68-11-202, 68-11-206, 68-11-209, 68-11-226, and 68-11-304.

Rule 0720-30-.11 Records and Reports is amended by adding new paragraph (5), so that as amended, the new paragraph shall read:

(5) Survey Material. The agency shall have written policies dealing with survey material. Survey material shall be immediately available upon request of a Commission surveyor to the electronic mail address on record with the Commission. Survey material is any material stored in electronic or physical format that may be necessary to conduct a survey. Survey material shall include, but is not limited to the following:

- (a) Personnel files;
- (b) Patient medical records;
- (c) Policies and procedures;
- (d) Data;
- (e) Background checks;
- (f) Abuse registry checks;

- (g) Facility reported incidents;
- (h) Litigation and bankruptcy history;
- (i) Current licensure status;
- (j) Copies of investigations;
- (k) Discipline records in any other state in which the provider is licensed;
- (l) Video records or files, if available.

Authority: T.C.A. §§ 68-11-202, 68-11-209, 68-11-211, 68-11-226, and 68-11-260.



\* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Paul C. Boyd				X	
Louis F. Caputo	X				
Howard Daniel Clark, D.D.S	X				
Patsy E. Crichfield	X				
Joshua A. Crisp	X				
James Dunn, Executive Director Commission on Aging and Disability				X	
Julie Jeter, M.D.				X	
Patricia P. Kettermann	X				
Tom Marshall				X	
Bobby G. Meadows	X				
Roger L. Mynatt	X				
Jennifer Tatum- Cranford, Pharm.D.				X	
Gina Throneberry				X	
Monica Warhaftig, D.O.	X				
Christopher Wilson, M.D., Chairman	X				
VACANT					
VACANT					
VACANT					
VACANT					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Health Facilities Commission, Board for Licensing Health Care Facilities on 08/30/2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 07/07/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 08/30/2023

Date: 2/6/2024

Signature: [Signature]


Name of Officer: Logan Grant

Title of Officer: Executive Director

Agency/Board/Commission: TN Health Facilities Commission, Board for Licensing Health Care Facilities

Rule Chapter Number(s): 0720-30

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

  
Jonathan Skrmetti  
Attorney General and Reporter

3-4-2024

Date

**Department of State Use Only**

Filed with the Department of State on: 3/4/2024

Effective on: 6/2/2024

  
Tre Hargett  
Secretary of State

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**Public Hearing Comments**

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

No public comments were made during the rulemaking hearing.



**Regulatory Flexibility Addendum**

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

(Insert statement here)

The proposed rule amendments are not expected to have an impact on small business.

### **Impact on Local Governments**

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

(Insert statement here)

The proposed rule amendments should not have a financial impact on local governments.

**Additional Information Required by Joint Government Operations Committee**

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rules add the definition of contact person, home medical equipment provider, and survey material. Additionally, the rule changes set forth the requirements for operation of the various category types, as well as how to convert a physical location to another category type.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Public Chapter 99 of 2023.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Any home care organization providing home medical equipment to residents of Tennessee.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

N/A

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

None.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Logan Grant, Executive Director

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Logan Grant, Executive Director

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

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- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.



**RULES  
OF  
THE TENNESSEE HEALTH FACILITIES COMMISSION**

**CHAPTER 0720-30  
STANDARDS FOR HOME CARE ORGANIZATIONS  
PROVIDING HOME MEDICAL EQUIPMENT**

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**0720-30-.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.

- (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) Contact Person. The individual selected by the agency who will serve as the point-of-contact to communicate with the Health Facilities Commission. The agency must provide a name, title, telephone number, and electronic mail address of the contact person on the appropriate form.

~~(12)~~ (13) 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)~~ (14) Department. The Tennessee Department of Health.

~~(14)~~ (15) 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)~~ (16) Evaluation. The determination and documentation of the physiological and functional factors that impact the selection of an appropriate seating and wheeled mobility device.

~~(16)~~ (17) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

~~(17)~~ (18) 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)~~ (19) 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 0720-30-.13 or T.C.A. § 33-3-220.

~~(19)~~ (20) 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)~~ (21) Home Medical Equipment.

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

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 defined 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.~~

(22) Home medical equipment provider. Any agency which provides home medical equipment services.



(a) Providers may fall into the following categories:

1. In-state providers who have a physical location;
2. In-state providers who have no physical location;
3. Out-of-state providers who do not have a physical location; or
4. Mail order companies.

(b) Providers who do not have a physical location must comply with survey requirements and provide access and documentation to surveyors necessary to conduct a survey.

(c) Designation on whether or not an agency has a physical location shall be located on the agency's wall certificate.

~~(22)~~ (23) 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)~~ (24) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

~~(24)~~ (25) 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)~~ (26) 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)~~ (27) 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)~~ (28) 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)~~ (29) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

~~(29)~~ (30) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

~~(30)~~ (31) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

~~(31)~~ (32) Mail Order Company. 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 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.

~~(32)~~ (33) 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.

~~(33)~~ (34) 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.

~~(34)~~ (35) 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.

~~(35)~~ (36) 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.

~~(36)~~ (37) 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.

~~(37)~~ (38) 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.



~~(38)~~ (39) 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.

~~(39)~~ (40) 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).

~~(40)~~ (41) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

~~(44)~~ (42) Shall or Must. Compliance is mandatory.

~~(42)~~ (43) 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.

~~(43)~~ (44) 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.

(45) Survey material. Survey material is any material stored in electronic or physical format that may be necessary to conduct a survey. The survey material includes, but is not limited to, personnel files, patient medical records, policies and procedures, data, background checks, abuse registry checks, facility reported incidents, litigation and bankruptcy history, current licensure status, copies of investigations, discipline records in any other state in which the provider is licensed, and video records or files, if available.

~~(44)~~ (46) 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. Amendments filed January 7, 2019; to have become effective April 7, 2019. However, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 6, 2019. Transferred from chapter 1200-08-29 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.

## 0720-30-.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.~~

- (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) A license shall be issued to the person or persons named and for the premises listed in the application for licensure, if a physical location in Tennessee is listed.
  - (b) The name of the home care organization providing home medical equipment shall not be changed without first notifying the Commission in writing.
  - (c) Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance.
  - (d) The license shall be conspicuously posted in the home care organization providing home medical equipment, if a physical location in Tennessee is listed.
  - (e) If a provider does not desire an in-state location, this information is required to be provided at the time of application.
- (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 four hundred and four dollars (\$1,404.00). The fee must be submitted with the initial application or renewal 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.~~
  - (f) The applicant, through the designated contact person, shall allow the home care organization providing home medical equipment to be inspected by a Commission surveyor and provide access to survey material. 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.
  - (g) If a physical location in Tennessee is not desired, the provider shall designate the type of category desired upon initial application.
- (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 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 0720-30-.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.

(5) Conversion of Designated License Category. If a licensee wishes to convert to a different designated license category under paragraph (22) of Rule 0720-30-.01, a Notice of Intent to Convert must be received by the Commission.

**Authority:** T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-206(a)(5), 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, § 1.

**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. Amendments filed March 26, 2019; effective June 24, 2019. Transferred from chapter 1200-08-29 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.

### 0720-30-.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;
  - ~~(d) Conduct or practices found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or~~
  - (d) Conduct or practices found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency;
  - ~~(e) Failure to renew the license.~~
  - (e) Failure to renew the license; and
  - (f) Failure to comply with survey document requests after three (3) written requests to the contact person are made by a surveyor.
- (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;



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.

- (5) When an agency contact person fails to respond to the third written request for documentation from a surveyor, the agency shall be subject to a civil monetary penalty ranging from five hundred dollars (\$500.00) to five thousand dollars (\$5,000.00), and disciplinary action up to revocation of the license. If the same violation has occurred within the last twelve (12) months, the civil monetary penalty may be doubled.

**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. Transferred from chapter 1200-08-29 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.

#### 0720-30.04 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.
- (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;
  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
  - (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.

(10) An agency without a physical location in Tennessee shall not be subject to the requirements of 0720-30-.04(7)-(9).

**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. Transferred from chapter 1200-08-29 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.



**0720-30-.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:
  - (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.
- (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 agency 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) Except for mail order companies, 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:~~

- ~~(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.~~

(5) Location.

(a) If a provider chooses to have a physical location in Tennessee, each parent and/or branch shall:

- 1. Be located in Tennessee;
- 2. Be staffed during normal business hours and have a working telephone;
- 3. Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;
- 4. Meet all local zoning requirements; and
- 5. Have all required current licenses and/or permits conspicuously posted in the agency.

(b) If an agency chooses not to have a physical location in Tennessee, each parent and/or branch shall:

- 1. Be licensed in Tennessee;
- 2. Be staffed during normal business hours and have a working telephone and electronic mail address;
- 3. Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;
- 4. Have all required current licenses with appropriate designation and/or permits available for inspection; and
- 5. Upon initial licensure, provide to the Commission the means and method of entry to a virtual portal for surveyors to access survey material.

- (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;
  - 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. Amendments filed January 7, 2019; to have become effective April 7, 2019. However, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 6, 2019. Transferred from chapter 1200-08-29 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.

#### 0720-30-.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.
- (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) Except for mail order companies, documentation of in-home 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.
- (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 policies 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 policies and procedures.

(5) Survey Material. The agency shall have written policies dealing with survey material. Survey material shall be immediately available upon request of a Commission surveyor to the electronic mail address on record with the Commission. Survey material is any material stored in electronic or physical format that may be necessary to conduct a survey. Survey material shall include, but is not limited to the following:

- (a) Personnel files;
- (b) Patient medical records;
- (c) Policies and procedures;

- (d) Data;
- (e) Background checks;
- (f) Abuse registry checks;
- (g) Facility reported incidents;
- (h) Litigation and bankruptcy history;
- (i) Current licensure status;
- (j) Copies of investigations;
- (k) Discipline records in any other state in which the provider is licensed;
- (l) Video records or files, if available.

**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. Amendments filed January 7, 2019; to have become effective April 7, 2019. However, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 6, 2019. Transferred from chapter 1200-08-29 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.