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Division of Publications**

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**For Department of State Use Only**

Sequence Number: 12-29-09  
Rule ID(s): 4587-4591  
File Date: 12/23/23  
Effective Date: 03/23/2010

# Rulemaking Hearing Rule(s) Filing Form

*Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205*

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Division of Health Care Facilities
<b>Contact Person:</b>	Lucille F. Bond
<b>Address:</b>	Office of General Counsel Tennessee Department of Health 220 Athens Way, Suite 210 Nashville, Tennessee
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**Revision Type (check all that apply):**

- Amendment  
 New  
 Repeal

**Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)**

Chapter Number	Chapter Title
1200-08-01	Standards for Hospitals
Rule Number	Rule Title
1200-08-01-.04	Administration
1200-08-01-.06	Basic Hospital Functions

Chapter Number	Chapter Title
1200-08-11	Standards for Homes for the Aged
Rule Number	Rule Title
1200-08-11-.10	Records and Reports

Chapter Number	Chapter Title
1200-08-14	Pediatric Trauma Centers
Rule Number	Rule Title
1200-08-14-.01	Purpose
1200-08-14-.02	Definitions
1200-08-14-.03	Requirements
1200-08-14-.04	Programs for Quality Assurance
1200-08-14-.05	Designation Process

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1200-08-14-.05	Designation Process

<b>Chapter Number</b>	<b>Chapter Title</b>
1200-08-27	Standards for Home Care Organizations Providing Hospice Services
<b>Rule Number</b>	<b>Rule Title</b>
1200-08-27-.01	Definitions
1200-08-27-.05	Admissions, Discharges and Transfers

<b>Chapter Number</b>	<b>Chapter Title</b>
1200-08-29	Standards for Home Care Organizations Providing Home Medical Equipment
<b>Rule Number</b>	<b>Rule Title</b>
1200-08-29-.01	Definitions
1200-08-29-.06	Basic Agency Functions

Chapter 1200-08-01  
Standards for Hospitals

Amendments

Rule 1200-08-01-.04 Administration is amended by deleting paragraph (3) in its entirety and substituting instead the following language, so that as amended, the new paragraph (3) shall read:

- (3) When licensure is applicable for a particular job, the number and renewal number of the current license or a copy of the internet verification of such license must be maintained in personnel. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-01-.06 Basic Hospital Functions is amended by adding the following language as new subparagraph (3)(g) and re-numbering the remaining subparagraphs appropriately, so that as amended, the new subparagraph (3)(g) shall read:

- (g) All hospitals shall each year from October 1 through March 1 offer the immunization for influenza and pneumococcal diseases to any inpatient who is sixty-five (65) years of age or older prior to discharging. This condition is subject to the availability of the vaccine.

Authority: T.C.A. § 68-11-209.

Chapter 1200-08-11  
Standards for Homes for the Aged

Amendments

Rule 1200-08-11-.10 Records and Reports is amended by deleting paragraph (1) and renumbering the remaining paragraphs appropriately.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-14  
Pediatric Trauma Centers

Repeals

Rule 1200-08-14-.01 Purpose is repealed.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-14-.02 Definitions is repealed.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-14-.03 Requirements is repealed.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-14-.04 Programs for Quality Assurance is repealed.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-14-.05 Designation Process is repealed.

Authority: T.C.A. § 68-11-209.

#### 1200-08-27

### Standards for Home Care Organizations Providing Hospice Services

#### Amendments

Rule 1200-08-27-.01 Definitions is amended by deleting paragraphs (31) and (45) in their entirety and substituting instead the following language, so that as amended, the new paragraphs (31) and (45) shall read:

- (31) Hospice Services. As defined by T.C.A. § 68-11-201, "hospice services," means a coordinated program of care, under the direction of an identifiable hospice administrator, providing palliative and supportive medical and other services to hospice patients and their families in the patient's regular or temporary place of residence. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week. "Hospice services" may also be provided to a non-hospice patient limited to palliative care only.
- (45) Patient. Hospice patient means only a person who has been diagnosed as terminally ill; been certified by a physician in writing to have an anticipated life expectancy of six (6) months or less; has voluntarily though self or a surrogate requested admission to a hospice; and been accepted by a licensed hospice. Patient will also include a non-hospice patient receiving only palliative care.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-27-.05 Admissions, Discharges and Transfers is amended by deleting subparagraph (1)(d) in its entirety and substituting instead the following language, and is further amended by adding the following language as new subparagraph (1)(e), so that as amended, the new subparagraphs (1)(d) and (1)(e) shall read:

- (d) Has personally or through a representative, in writing, given informed consent to receive hospice care; or
- (e) Is a non-hospice patient that has been determined to need palliative care only.

Authority: T.C.A. § 68-11-209.

#### Rule 1200-08-29

### Standards for Home Care Organizations Providing Home Medical Equipment

#### Amendments

Rule 1200-08-29-.01 Definitions is amended by deleting paragraph (43) in its entirety and substituting instead

the following language, so that as amended, the new paragraph (43) shall read:

- (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. § 68-11-209.

Rule 1200-08-29-.01 Definitions is amended by deleting paragraph (12) and renumbering the remaining paragraphs appropriately.

**Authority:** T.C.A. § 68-11-209.

Rule 1200-08-29-.01 Definitions is amended by adding the following language as a new, appropriately numbered paragraph, so that as amended, the new, appropriately numbered paragraph shall read:

- ( ) **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).

**Authority:** T.C.A. § 68-11-209.

Rule 1200-08-29-.06 Basic Agency Functions is amended by deleting subparagraph (6)(b) in its entirety and substituting instead the following language, and is further amended by adding the following language as new subparagraphs (6)(c) through (6)(f) and re-numbering the remaining subparagraphs appropriately, so that as amended, the new subparagraphs (6)(b) through (6)(f) shall read:

- (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.

**Authority:** T.C.A. § 68-11-209.

\* 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)
Larry Arnold, M.D.			X		
Duane Budd, M.D.	X				
Charlotte Burns				X	
Thomas Carr, M.D.	X				
Elizabeth Chadwell	X				
Alex Gaddy			X		
Estelle Garner	X				
Robert Gordon	X				
C. Luke Gregory	X				
Norman E. Jones, M.D.	X				
Charlsie H. Lankford				X	
Carissa S. Lynch, D. PH.	X				
Annette Marlar, R.N.	X				
Sara Snodgrass	X				
Ronald C. Staples, D.D.S.	X				
Joe T. Walker, D.D.S.				X	
Carlyle L.E. Walton				X	
James V. Weatherington				X	
Jon Winter, D.O.				X	
Kathy Zamata				X	

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board for Licensing Health Care Facilities on 11/14/2007, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 08/03/07

Notice published in the Tennessee Administrative Register on: 09/15/07

Rulemaking Hearing(s) Conducted on: (add more dates). 10/16/07

Date: 12/14/09

Signature: Lucille F. Bond

Name of Officer: Lucille F. Bond

Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 12/14/09



Notary Public Signature: Theodora P. Williams

My commission expires on: 11/7/2011

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.

Robert E. Cooper, Jr.

Robert E. Cooper, Jr.  
Attorney General

12-22-09

Date

**Department of State Use Only**

Filed with the Department of State on: 12/23/09

Effective on: 3/23/10

Tre Hargett

Tre Hargett  
Secretary of State

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PUBLICATIONS

## **Public Hearing Comments**

No comments were received at the Rulemaking hearing. (See attached.)

## Regulatory Flexibility Addendum

Pursuant to Public Chapter 464 of the 105<sup>th</sup> General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

### Regulatory Flexibility Analysis

- (1) The affected businesses are Hospitals, Homes for the Aged, Hospice, Home Medical Equipment, and Pediatric Trauma Centers licensed in the state of Tennessee. The ascribed definition of small business may only affect the licensed Homes for the Aged, Hospice, and Home Medical Equipment facility types. As of November 30, 2007, Tennessee had one hundred twenty-two (122) licensed Homes for the Aged, three hundred fourteen (314) licensed Home Medical Equipment facilities, and fifty-nine (59) licensed Hospice facilities. The Home for the Aged will benefit from the reduction of staff time in completing a Joint Annual Report which as these rules propose will be removed. The Hospice facilities will not have any impact as a result of the proposed rule language. The Home Medical Equipment facilities will benefit from further clarification offered by the proposed rule language for qualified rehabilitation professionals and additional compliance requirements. Hospital and Pediatric Trauma Center have fifty (50) or more employees.
- (2) The proposed amendments have no increased or new reporting, recordkeeping, or other administrative costs that are required for compliance.
- (3) The proposed amendments shall have only positive effects on small businesses and consumers in that a broader level of service can be provided by the Hospice facilities, better definition and compliance requirements for Home Medical Equipment facilities will be established, and a reduction of required report completion for Home for the Aged. Even though the following two facility types have more than fifty (50) employees there will still be positive effects of the proposed rule amendments – the removal of duplication of regulations by repealing the Pediatric Trauma Center regulations and the offer of more flexibility with staff licensure verification by the proposed rules for Hospitals.
- (4) The Board does not believe there are less burdensome alternatives to the proposed rule amendments . The proposed rule amendments for the Hospice and Home Medical Equipment facilities are derived for laws passes during the last legislative session. The Homes for the Aged proposed rule amendment are to correct a misnomer in the current regulations. The ascribed definition of small business does not include Hospitals and Pediatric Trauma Centers which have more than fifty (50) employees. Still, given this conclusion the Board does not believe there are less burdensome alternative to the Hospital and Pediatric Trauma Center proposed rule amendments.
- (5) The Board is not aware of any federal counterparts.
- (6) It is not possible to exempt small businesses from the requirements contained in the proposed rule because the rule amendments directly affect all licensed Hospice and Home Medical Equipment facilities and Homes for the Aged with any number of employees as well as Hospitals and Pediatric Trauma Centers which have fifty (50) or more employees.

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

All agencies, upon filing a rule, must also submit the following pursuant to TCA 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;

1200-8-01-.04 Administration—The old rule did not include that a copy of the internet verification of license maintained in personnel is acceptable for licensed personnel. The new rule includes the above.
1200-8-01-.06 Basic Hospital Functions—The old rule did not include that all hospitals shall each year from October 1 through March 1 offer the immunization for influenza and pneumococcal diseases to any inpatient who is sixty-five (65) years of age or older prior to discharging and is subject to availability of the vaccine. The new rule includes the above.
1200-08-11-.10 Records and Reports—The old rule includes the requirement of the yearly statistical report of “Joint Annual Report of Home for the Aged.” The new rule deletes the above requirement.
1200-08-14.01 Purpose—The rule is repealed.
1200-08-14-.02 Definitions—The rule is repealed.
1200-08-14-.03 Requirements—The rule is repealed.
1200-08-14-.04 Programs for Quality Assurance—The rule is repealed.
1200-08-27-.01 Definitions—The old rule did not include in the definitions of Hospice Services and Patient that hospice services may also be provided to a non-hospice patient limited to palliative care only. The new rule includes the above.
1200-08-27-.05 Admissions, Discharges and Transfers—The old rule did not include that a non-hospice patient receiving only palliative care may be admitted. The new rule includes the above.
1200-08-29-.01 Definitions—the old rule includes the definition of Credentialed Wheeled Mobility Person. The new rule deletes the above definition. The old rule did not include the definition of Qualified Rehabilitation Professional. The new rule includes the definition of Qualified Rehabilitation Professional. The old rule did not include in the definition of Wheeled Mobility Device the exemption of a Medicare wheelchair with a base code of K0007 as long as the consumer weighs less than three hundred (300) pounds. The new rule includes the above exemption.
1200-08-29-.06 Basic Agency Functions—The old rule did not include under additional compliance requirements the following: face-to-face written evaluation by a qualified rehabilitation professional for consumers of prescribed wheeled mobility devices (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.); agency requirement of a qualified rehabilitation professional on staff or contract and as of June 8, 2007, a 180 day grace period for agencies if qualified rehabilitation professional ceases to be employed and the agency has no other qualified rehabilitation professional on staff; agencies required to have a repair service department or a contract with a repair service department in the state of Tennessee if prescribed wheeled mobility devices are made available to the consumers by the agencies; agency required to have a qualified technician with knowledge and capability of servicing the product provided to consumer; delivery and final fitting of a wheeled mobility device shall be determined by a qualified rehabilitation professional. The new rule includes the above additional compliance requirements.

- (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;

T.C.A. § 68-11-209 grants the Board for Licensing Health Care Facilities the duty and power to promulgate rules and regulations pertaining to the operation of health care facilities as are necessary to the public interest.

- (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;

The Board for Licensing Health Care Facilities urges the adoption of the above rule amendments and repeals.

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

None

**(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;

I, as well as Vincent Davis, Director, Division of Health Care Facilities possess substantial knowledge and understanding of the rule.

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

I, as well as Vincent Davis, Director, Division of Health Care Facilities will explain the rule at a scheduled meeting of the committees.

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

Lucille F. Bond, Assistant General Counsel, Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243, (615) 741-1611  
Vincent Davis, Director, Division of Health Care Facilities, Tennessee Department of Health, Bureau of Health Licensure and Regulation, 227 French Landing, Suite 501, Nashville, TN 37243 (615) 741-7221

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

None

(Rule 1200-8-1-.03, continued)

- (b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;
  - (c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and
  - (d) Any prior violations by the facility of statutes, regulations or orders of the board.
- (3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke a hospital's license.
- (4) When a hospital is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the deficiencies, the hospital must return a plan of correction indicating the following:
- (a) How the deficiency will be corrected;
  - (b) The date upon which each deficiency will be corrected;
  - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
  - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.
- (5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the hospital's license to possible disciplinary action.
- (6) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §4-5-101, et seq.
- (7) **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 1360-4-1-.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, 68-11-206, 68-11-208, 68-11-209, and 68-11-216. **Administrative History:** Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. The following is a copy of T.C.A. §53-1317: Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed December 30, 1986; effective February 13, 1987. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed March 1, 2007; effective May 15, 2007.

#### **1200-8-1-.04 ADMINISTRATION.**

- (1) The hospital must have an effective governing body legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this chapter.
- (2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital. The chief executive officer or administrator shall designate an individual to act for him or her in his or her absence, in order to provide the hospital with administrative direction at all times.

(Rule 1200-8-1-.04, continued)

- ~~(3) When licensure is applicable for a particular job, the number and renewal number of the current license must be maintained in personnel. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee. (Delete.)~~
- (3) When licensure is applicable for a particular job, the number and renewal number of the current license or a copy of the internet verification of such license must be maintained in personnel. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.
- (4) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A hospital which violates a required policy also violates the rule and regulation establishing the requirement.
- (5) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (6) No hospital shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the department, the Adult Protective Services, or the Comptroller of the State Treasury. A hospital shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.
- (7) The hospital shall ensure a framework for addressing issues related to care at the end of life.
- (8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.
- (9) Critical Access Hospital.
- (a) The facility shall enter into agreements with one or more hospitals participating in the Medicare/Medicaid programs to provide services which the Critical Access Hospital is unable to provide.
- (b) When there are no inpatients, the facility is not required to be staffed by licensed medical professionals, but must maintain a receptionist or other staff person on duty to provide emergency communication access. The hospital shall provide an effective system to ensure that a physician or a mid-level practitioner with training and experience in emergency care is on call and immediately available by telephone or radio and available on site within thirty (30) minutes, twenty-four (24) hours a day.
- (10) 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

(Rule 1200-8-1-.04, continued)

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.

- (11) Hospice services may be provided in an area designated by a hospital for exclusive use by a home care organization certified as a hospice provider to provide care at the hospice inpatient or respite level of care in accordance with the hospice's Medicare certification. Admission to the hospital is not required in order for a patient to receive such hospice services, regardless of the patient's length of stay. The designation by a hospital of a portion of its facility for exclusive use by a home care organization to provide hospice services to its patients shall not:
  - (a) alter the license to bed complement of such hospital, or
  - (b) result in the establishment of a residential hospice.

**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, 68-11-216, and 71-6-121. **Administrative History:** Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007.

#### 1200-8-1-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

- (1) Every person admitted for care or treatment to any hospital covered by these rules shall be under the supervision of a physician who holds an unlimited license to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.
- (2) The above does not preclude the admission of a patient to a hospital by a dentist or podiatrist or certified nurse midwife licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.
- (3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.
- (4) A diagnosis must be entered in the admission records of the hospital for every person admitted for care or treatment.
- (5) Except in emergencies, no medication or treatment shall be given or administered to any patient in a hospital except on the order of a physician, dentist or podiatrist lawfully authorized to give such an order.
- (6) The facility 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 subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.
- (7) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established hospital protocol or rules.

(Rule 1200-8-1-.05, continued)

- (e) However, if department staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled board meeting to justify the need for exceeding its licensed bed capacity.

(24) Infant Abandonment.

- (a) Any hospital shall receive possession of any newborn infant left on hospital premises with any hospital employee or member of the professional medical community, if the infant:
  - 1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;
  - 2. Is left in an unharmed condition; and
  - 3. Is voluntarily left by a person who purported to be the child's mother and who did not express an intention of returning for the infant.
- (b) The hospital, any hospital employee and any member of the professional medical community at such hospital shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The hospital shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The hospital may provide the parent contact information regarding relevant social service agencies, shall provide the mother the name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinquishment of the infant. If practicable, the hospital shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.
- (c) The hospital, any hospital employee and any member of the professional medical community at such hospital shall perform any act necessary to protect the physical health or safety of the child.
- (d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the hospital shall contact the Department of Children's Services, but shall not do so before the mother leaves the hospital premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.
- (e) Notwithstanding any provision of law to the contrary, any hospital, any hospital employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause of action based upon violation of such existing standard of care for medical treatment.

**Authority:** T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, and 68-11-255. **Administrative History:** Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002.

**1200-8-1-.06 BASIC HOSPITAL FUNCTIONS.**

- (1) Performance Improvement.

(Rule 1200-8-1-.06, continued)

- (a) The hospital must ensure that there is an effective, hospital-wide performance improvement program to evaluate and continually improve patient care and performance of the organization.
  - (b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:
    1. All organized services including services furnished by a contractor, are evaluated (all departments including engineering, housekeeping, and accounting need to show evidence of process improvement.);
    2. Nosocomial infections and medication therapy are evaluated;
    3. All medical and surgical services performed in the hospital are evaluated as to the appropriateness of diagnosis and treatment;
    4. The competency of all staff is evaluated at least annually; and
    5. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program, central venous catheter insertion process, and influenza vaccination program.
  - (c) The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients which assures that:
    1. Discharge planning is initiated in a timely manner; and
    2. Patients, along with their necessary medical information, are transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.
  - (d) The hospital must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action.
  - (e) The hospital must demonstrate that the appropriate governing board or board committee is regularly apprised of process improvement activities, including identified deficiencies and the outcomes of remedial action.
- (2) Medical Staff.
- (a) The hospital shall have an organized medical staff operating under bylaws adopted by the medical staff and approved by the governing body, to facilitate the medical staff's responsibility in working toward improvement of the quality of patient care.
  - (b) The hospital and medical staff bylaws shall contain procedures, governing decisions or recommendations of appropriate authorities concerning the granting, revocation, suspension, and renewal of medical staff appointments, reappointments, and/or delineation of privileges. At a minimum, such procedures shall include the following elements: A procedure for appeal and hearing by the governing body or other designated committee if the applicant or medical staff feels the decision is unfair or wrong.
  - (c) The governing body shall be responsible for appointing medical staff and for delineating privileges. Criteria for appointment and delineation of privileges shall be clearly defined and included in the medical staff bylaws, and related to standards of patient care, patient welfare, the

(Rule 1200-8-1-.06, continued)

objectives of the institution or the character or competency of the individual practitioner. Independent patient admission privileges shall only be granted to currently licensed doctors of medicine, osteopathy, podiatry, or dentistry.

- (d) The medical staff must adopt and enforce bylaws to effectively carry out its responsibilities and the bylaws must:
  - 1. Be approved by the governing body;
  - 2. Include a statement of the duties and privileges of each category of medical staff;
  - 3. Describe the organization of the medical staff;
  - 4. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;
  - 5. Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges; and
  - 6. Include provisions for medical staff appointments granting active, associate, or courtesy medical staff membership, and/or provisions for the granting of clinical privileges. Such individuals must practice within the scope of their current Tennessee license, and the overall care of each patient must be under the supervision of a physician member of the medical staff.
- (e) To be eligible for staff membership, an applicant must be a graduate of an approved program of medicine, dentistry, osteopathy, podiatry, optometry, psychology, or nurse-midwifery, currently licensed in Tennessee, competent in his or her respective field, and worthy in character and in matters of professional ethics.
- (f) The medical staff shall be composed of currently licensed doctors of medicine, osteopathy, dentistry, and podiatry and may include optometrists, psychologists, and nurse-midwives. The medical staff must:
  - 1. Periodically conduct appraisals of its members;
  - 2. Examine the credentials of candidates for medical staff membership and make recommendations to the hospital on the appointment of the candidates; and
  - 3. Participate actively in the hospital's process improvement plan implementation for the improvement of patient care delivery plans.
- (g) The medical staff must be structured in a manner approved by the hospital or its governing body, well organized, and accountable to the hospital for the quality of the medical care provided to the patient. Disciplinary action involving medical staff taken by the hospital shall be reported to the appropriate licensing board or professional society.
- (h) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.
- (i) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy, or a doctor of dental surgery or dental medicine.
- (j) All physicians and non-employee medical personnel working in the hospital must adhere to the policies and procedures of the hospital. The chief executive officer or his or her designee shall

(Rule 1200-8-1-.06, continued)

provide for the adequate supervision and evaluation of the clinical activities of non-employee medical personnel which occur within the responsibility of the medical staff service.

(3) Infection Control.

- (a) The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.
- (b) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develop guidelines and techniques for the prevention, surveillance, control and reporting of hospital infections. Duties of the committee shall include the establishment of:
  1. Written infection control policies;
  2. Techniques and systems for identifying, reporting, investigating and controlling infections in the hospital;
  3. Written procedures governing the use of aseptic techniques and procedures in all areas of the hospital, including adoption of a standardized central venous catheter insertion process which shall contain these key components:
    - (i) Hand hygiene (as defined in 1200-8-1-.06(3)(g));
    - (ii) Maximal barrier precautions to include the use of sterile gowns, gloves, mask and hat, and large drape on patient;
    - (iii) Chlorhexidine skin antisepsis;
    - (iv) Optimal site selection;
    - (v) Daily review of line necessity; and
    - (vi) Development and utilization of a procedure checklist;
  4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;
  5. A log of incidents related to infectious and communicable diseases;
  6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;
  7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and
  8. Continuing education provided for all hospital personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.

(Rule 1200-8-1-.06, continued)

- (c) The administrative staff shall ensure the hospital prepares, and has readily available on site, an Infection Control Risk Assessment for any renovation or construction within existing hospitals. Components of the Infection Control Risk Assessment may include, but are not limited to, identification of the area to be renovated or constructed, patient risk groups that will potentially be affected, precautions to be implemented, utility services subject to outages, risk of water damage, containment measures, work hours for project, management of traffic flow, housekeeping, barriers, debris removal, plans for air sampling during or following project, anticipated noise or vibration generated during project.
- (d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the hospitalwide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.
- (e) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
- (f) The facility shall have an annual influenza vaccination program which shall include at least:
  - 1. The offer of influenza vaccination to all staff and independent practitioners or accept documented evidence of vaccination from another vaccine source or facility;
  - 2. A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;
  - 3. Education of all direct care personnel 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;
  - 5. The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.
- (g) All hospitals shall each year from October 1 through March 1 offer the immunization for influenza and pneumococcal diseases to any inpatient who is sixty-five (65) years of age or older prior to discharging. This condition is subject to the availability of the vaccine.
- ~~(g)~~ The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:
  - 1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;

(Rule 1200-8-1-.06, continued)

2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;
  3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and
  4. Health care worker education programs which may include:
    - (i) Types of patient care activities that can result in hand contamination;
    - (ii) Advantages and disadvantages of various methods used to clean hands;
    - (iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and
    - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (h) All hospitals shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
- (i) Each department of the hospital performing decontamination and sterilization activities must develop policies and procedures in accordance with the current editions of the CDC guidelines for "Prevention and Control of Nosocomial Diseases" and "Isolation in Hospitals".
- (j) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including:
1. Receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing reusable items;
  2. Assembling, wrapping, removal of outer shipping cartons, storage, distribution, and quality control of sterile equipment and medical supplies;
  3. Proper utilization of sterilization process monitors, including temperature and pressure recordings, and use and frequency of appropriate chemical indicator or bacteriological spore tests for all sterilizers; and
  4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies;
  5. Procedures for recall and disposal or reprocessing of sterile supplies; and
  6. Procedures for emergency collection and disposition of supplies and the timely notification of attending physicians, general medical staff, administration and the hospital's risk management program when special warnings have been issued or when warranted by the hospital's performance improvement process.
- (k) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Sterile supplies may not be stored in their outermost shipping carton. This would

(Rule 1200-8-1-.06, continued)

include both hospital and commercially prepared supplies. Decontamination and preparation areas shall be separated.

- (l) Space and facilities for housekeeping equipment and supply storage shall be provided in each hospital service area. Storage for bulk supplies and equipment shall be located away from patient care areas. Storage shall not be allowed in the outermost shipping carton. The building shall be kept in good repair, clean, sanitary and safe at all times.
- (m) The hospital shall appoint a housekeeping supervisor who is qualified for the position by education, training and experience. The housekeeping supervisor shall be responsible for:
  1. Organizing and coordinating the hospital's housekeeping service;
  2. Acquiring and storing sufficient housekeeping supplies and equipment for hospital maintenance;
  3. Assuring the clean and sanitary condition of the hospital to provide a safe and hygienic environment for patients and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and hospital policy; and
  4. Verifying regular continuing education and competency for basic housekeeping principles.
- (n) Laundry facilities located in the hospital shall:
  1. Be equipped with an area for receiving, processing, storing and distributing clean linen;
  2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;
  3. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the hospital. Linen may not be stored in cardboard containers or other containers which offer housing for bugs; and,
  4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.
- (o) The hospital shall appoint a laundry service supervisor who is qualified for the position by education, training and experience. The laundry service supervisor shall be responsible for:
  1. Establishing a laundry service, either within the hospital or by contract, that provides the hospital with sufficient clean, sanitary linen at all times;
  2. Knowing and enforcing infection control rules and regulations for the laundry service;
  3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures;
  4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures; and,
  5. Conducting periodic inspections of any contract laundry facility.

(Rule 1200-8-1-.06, continued)

- (p) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.
  - 1. Any condition on the hospital site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
  - 2. Cats, dogs or other animals shall not be allowed in any part of the hospital except for specially trained animals for the handicapped and except as addressed by facility policy for pet therapy programs. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.
  - 3. A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
  - 4. Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.
  - 5. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
  - 6. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.
- (4) Nursing Services.
  - (a) The hospital must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times.
  - (b) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The chief nursing officer must be a licensed registered nurse who is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.
  - (c) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.
  - (d) There must be a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licenses.
  - (e) A registered nurse must assess, supervise and evaluate the nursing care for each patient.
  - (f) The hospital must ensure that an appropriate individualized plan of care is available for each patient.

(Rule 1200-8-1-.06, continued)

- (g) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. All nursing personnel assigned to special care units shall have specialized training and a program in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed, along with documentation of annual competency skills.
  - (h) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
    - 1. the deceased was a patient at a hospital as defined by T.C.A. §68-11-201(27);
    - 2. death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;
    - 3. the nurse is licensed by the state; and
    - 4. the nurse is employed by the hospital providing services to the deceased.
  - (i) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The chief nursing officer must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. Annual competency and skill documentation must be demonstrated on these individuals just as employees, if they perform clinical activities.
  - (j) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.
  - (k) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they must be:
    - 1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and
    - 2. Signed or initialed by the prescribing practitioner according to hospital policy.
  - (l) Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.
  - (m) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.
- (5) Medical Records.
- (a) The hospital shall comply with the Tennessee Medical Records Act, T.C.A. §68-11-301, et seq. A hospital shall transfer copies of patient medical records in a timely manner to requesting practitioners and facilities.
  - (b) The hospital must have a medical record service that has administrative responsibility for medical records. The service shall be supervised by a Registered Record Administrator (RRA),

(Rule 1200-8-1-.06, continued)

an Accredited Record Technician, or a person qualified by work experience. A medical record must be maintained for every individual evaluated or treated in the hospital.

- (c) The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing and retrieval of records.
- (d) The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.
- (e) All medical records, either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years, or for the period of minority plus one year for newborns, after which such records may be destroyed. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of its contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the hospital's policies and procedures, and no record may be destroyed on an individual basis.
- (f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the department. Upon transfer to the department, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.
- (g) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.
- (h) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with federal and state laws, court orders or subpoenas.
- (i) The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.
- (j) All entries must be legible, complete, dated and authenticated according to hospital policy.
- (k) All records must document the following:
  - 1. Evidence of a physical examination, including a health history, performed and/or updated no more than forty-five (45) days prior to admission or within forty-eight (48) hours following admission;
  - 2. Admitting diagnosis;
  - 3. Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;
  - 4. Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;

(Rule 1200-8-1-.06, continued)

5. Properly executed informed consent forms for procedures and treatments specified by hospital policy, or by federal or state law if applicable, as requiring written patient consent;
  6. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;
  7. Discharge summary with outcome of hospitalization, disposition of case and plan for follow-up care; and
  8. Final diagnosis with completion of medical records within thirty (30) days following discharge.
- (l) Electronic and computer-generated records and signature entries are acceptable.
- (6) Pharmaceutical Services.
- (a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.
  - (b) A full-time, part-time or consulting pharmacist must be responsible for developing, supervising and coordinating all the activities of the pharmacy services.
  - (c) Current and accurate records must be kept of receipt and disposition of all scheduled drugs.
  - (d) Adverse drug events, both adverse reactions and medication errors, shall be reported according to established guidelines to the hospital performance improvement/risk management program and as appropriate to physicians, the hospital governing body and regulatory agencies.
  - (e) Abuses and losses of controlled substances must be reported, in accordance with federal and state laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.
  - (f) Current reference materials relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff in the pharmacy and in areas where medication is administered.
  - (g) Any unused portions of prescriptions shall be either turned over to the patient only on a written authorization including directions by the physician, or returned to the pharmacy for proper disposition by the pharmacist.
  - (h) Whenever patients bring drugs into an institution, such drugs shall not be administered unless they can be identified and ordered to be given by a physician.
- (7) Radiologic Services.
- (a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.
  - (b) The radiologic services must be free from hazards for patients and personnel.

(Rule 1200-8-1-.06, continued)

- (c) Patients, employees and the general public shall be provided protection from radiation in accordance with "State Regulations for Protection Against Radiation". All radiation producing equipment shall be registered and all radioactive material shall be licensed by the Division of Radiological Health of the Tennessee Department of Environment and Conservation.
  - (d) Periodic inspections of equipment must be made and hazards identified must be promptly corrected.
  - (e) Radiologic services must be provided only on the order of practitioners with clinical privileges or of other practitioners authorized by the medical staff and the governing body to order the services.
  - (f) X-ray personnel shall be qualified by education, training and experience for the type of service rendered.
  - (g) All x-ray equipment must be registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health.
  - (h) X-rays shall be retained for four (4) years and may be retired thereafter provided that a signed interpretation by a radiologist is maintained in the patient's record under T.C.A. § 68-11-305.
  - (i) Patients must not be left unattended in pre and post radiology areas.
- (8) Laboratory Services.
- (a) The hospital must maintain, or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act. All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.
  - (b) Emergency laboratory services must be available 24 hours a day.
  - (c) A written description of services provided must be available to the medical staff.
  - (d) The laboratory must make provision for proper receipt and reporting of tissue specimens.
  - (e) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.
  - (f) Laboratory services must be provided in keeping with services rendered by the hospital. This shall include suitable arrangements for blood and plasma at all times. Written policies and procedures shall be developed in concert with the Standards of American Association of Blood Banks. Documentation and record keeping shall be maintained for tracking and performance monitoring.
- (9) Food and Dietetic Services.
- (a) The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. A hospital may contract with an outside food management company if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies

(Rule 1200-8-1-.06, continued)

affecting patient treatment. If an outside contract is utilized for management of its dietary services, the hospital shall designate a full-time employee to be responsible for the overall management of the services.

- (b) The hospital must designate a person to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:
  - 1. A dietitian; or
  - 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or
  - 3. A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian.
- (c) There must be a qualified dietitian, full time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the patient and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.
- (d) There must be sufficient administrative and technical personnel competent in their respective duties.
- (e) Menus must meet the needs of the patients.
  - 1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.
  - 2. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioners or practitioners responsible for the care of the patients.
  - 3. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.
- (f) Education programs, including orientation, on-the-job training, inservice education, and continuing education programs shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in personal hygiene, proper inspection, handling, preparation and serving of food and equipment.
- (g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs.
- (h) All food shall be from sources approved or considered satisfactory by the department and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.
- (i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to

(Rule 1200-8-1-.06, continued)

prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual".

- (j) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.
- (10) Critical Access Hospital.
- (a) Every patient shall be under the care of a physician or under the care of a mid-level practitioner supervised by a physician.
  - (b) Whenever a patient is admitted to the facility by a mid-level practitioner, the supervising physician shall be notified of that fact, by phone or otherwise, and within 24 hours the supervising physician shall examine the patient or before discharge if discharged within 24 hours, and a plan of care shall be placed in the patient's chart, unless the patient is transferred to a higher level of care within 24 hours.
  - (c) A physician, a mid-level practitioner or a registered nurse shall be on duty and physically available in the facility when there are inpatients.
  - (d) A physician on staff shall:
    - 1. Provide medical direction to the facility's health care activities and consultation for non-physician health care providers.
    - 2. In conjunction with the mid-level practitioner staff members, participate in developing, executing, and periodically reviewing the facility's written policies and the services provided to patients.
    - 3. Review and sign the records of each patient admitted and treated by a practitioner no later than fifteen (15) days after the patient's discharge from the facility.
    - 4. Provide health care services to the patients in the facility, whenever needed and requested.
    - 5. Prepare guidelines for the medical management of health problems, including conditions requiring medical consultation and/or patient referral.
    - 6. At intervals no more than two (2) weeks apart, be physically present in the facility for a sufficient time to provide medical direction, medical care services, and staff consultation as required.
    - 7. When not physically present in the facility, either be available through direct telecommunication for consultation and assistance with medical emergencies and patient referral, or ensure that another physician is available for this purpose.
    - 8. The physical site visit for a given two week period is not required if, during that period, no inpatients have been treated in the facility.
  - (e) A mid-level practitioner on staff shall:
    - 1. Participate in the development, execution, and periodic review of the guidelines and written policies governing treatment in the facility.

(Rule 1200-8-1-.06, continued)

2. Participate with a physician in a review of each patient's health records.
  3. Provide health care services to patients according to the facility's policies.
  4. Arrange for or refer patients to needed services that are not provided at the facility.
  5. Assure that adequate patient health records are maintained and transferred as necessary when a patient is referred.
- (f) The Critical Access Hospital, at a minimum, shall provide basic laboratory services essential to the immediate diagnosis and treatment of patients, including:
1. Chemical examinations of urine stick or tablet methods, or both (including urine ketoses);
  2. Microscopic examinations of urine sediment;
  3. Hemoglobin or hematocrit;
  4. Blood sugar;
  5. Gram stain;
  6. Examination of stool specimens for occult blood;
  7. Pregnancy test;
  8. Primary culturing for transmittal to a CLIA certified laboratory;
  9. Sediment rate; and,
  10. CBC.

**Authority:** T.C.A. §§4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.  
**Administrative History:** Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed July 18, 2007; effective October 1, 2007.

#### 1200-8-1-.07 OPTIONAL HOSPITAL SERVICES.

- (1) Surgical Services.
  - (a) If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
  - (b) The organization of the surgical services must be appropriate to the scope of the services offered.
  - (c) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.
  - (d) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(Rule 1200-8-11-.09, continued)

- (a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfecting cycle must contain appropriate indicators to assure that conditions were met for proper sterilization or disinfection or materials included in the cycle, and appropriate records kept. Proper operation of such devices must be verified at least monthly, and records of the monthly verifications shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.
  - (b) A facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §§ 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.
  - (c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.
- (9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.
  - (10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this rule.
  - (11) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material, and shall be kept on elevated platforms.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209. **Administrative History:** Original rule filed June 21, 1979; effective August 6, 1979. Repeal and new rule filed July 27, 2000; effective October 10, 2000.

#### 1200-8-11-.10 RECORDS AND REPORTS.

- (1) ~~A yearly statistical report, the "Joint Annual Report of Homes for the Aged", shall be submitted to the department. The forms are mailed to each home for the aged by the department each year. The forms must be completed and returned to the department within sixty (60) days following receipt of the form. (Delete.)~~
- (2) An individual resident file shall be maintained for each resident in the home. Personal information shall be confidential and shall not be disclosed, except to the resident, the department and others with

(Rule 1200-8-11-.10, continued)

written authorization from the resident. These files shall be retained for one (1) year after the resident is transferred or discharged. The resident file shall include:

- (a) Name, Social Security Number, veteran status and number, marital status, age, sex, previous address and any health insurance provider and number, including Medicare and Medicaid numbers;
  - (b) Name, address and telephone number of next of kin, legal guardian and any other person identified by the resident to contact on his/her behalf;
  - (c) Name, address and telephone number of any person or agency providing additional services to the resident;
  - (d) Date of admission, transfer, discharge and any new forwarding address;
  - (e) Name and address of the resident's preferred physician, hospital, pharmacist, assisted care living facility and nursing home, and any other instructions from the resident to be followed in case of emergency;
  - (f) Record of all monies and other valuables entrusted to the home for safekeeping, with appropriate updates;
  - (g) Health information including all current prescriptions, major changes in resident's habits or health status, results of physician's visits, and any health care instructions; and
  - (h) A copy of the admission agreement signed and dated by the resident.
- (3) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.
- (a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:
    1. medication errors;
    2. aspiration in a non-intubated patient related to conscious/moderate sedation;
    3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;
    4. volume overload leading to pulmonary edema;
    5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;
    6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;
    7. burns of a second or third degree;

(Rule 1200-8-11-.10, continued)

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;
  9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:
    - (i) procedure related injury requiring repair or removal of an organ;
    - (ii) hemorrhage;
    - (iii) displacement, migration or breakage of an implant, device, graft or drain;
    - (iv) post operative wound infection following clean or clean/contaminated case;
    - (v) any unexpected operation or reoperation related to the primary procedure;
    - (vi) hysterectomy in a pregnant woman;
    - (vii) ruptured uterus;
    - (viii) circumcision;
    - (ix) incorrect procedure or incorrect treatment that is invasive;
    - (x) wrong patient/wrong site surgical procedure;
    - (xi) unintentionally retained foreign body;
    - (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;
    - (xiii) criminal acts;
    - (xiv) suicide or attempted suicide;
    - (xv) elopement from the facility;
    - (xvi) infant abduction, or infant discharged to the wrong family;
    - (xvii) adult abduction;
    - (xviii) rape;
    - (xix) patient altercation;
    - (xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;
    - (xxi) restraint related incidents; or
    - (xxii) poisoning occurring within the facility.
- (b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

(Rule 1200-8-11-.10, continued)

1. strike by the staff at the facility;
  2. external disaster impacting the facility;
  3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and
  4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.
- (c) For health services provided in a “home” setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.
- (d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department’s approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.
- (e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner’s representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.
- (f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.
- (g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.
- (h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as “other” with the facility explaining the facts related to the event or incident.

(Rule 1200-8-11-.10, continued)

- (i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.
  - (j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.
  - (k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.
  - (l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.
- (4) Legible copies of the following records and reports shall be retained in the facility, shall be maintained in a single file, and shall be made available for inspection during normal business hours for thirty-six (36) months following their issuance. Each resident and each person assuming any financial responsibility for a resident must be fully informed, before admission, of their existence in the home and given the opportunity to inspect the file before entering into any monetary agreement with the facility.
- (a) Local fire safety inspections;
  - (b) Local building code inspections, if any;
  - (c) Department licensure and fire safety inspections and surveys;
  - (d) Orders of the Commissioner or Board, if any; and
  - (e) Maintenance records of all safety equipment.

**Authority:** T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213. **Administrative History:** Original rule filed June 21, 1979; effective August 6, 1979. Amendment filed February 26, 1985; effective March 28, 1985. Amendment filed August 16, 1988; effective September 30, 1988. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003.

**1200-8-11-11 RESIDENT RIGHTS.** Each resident has at least the following rights:

- (1) To privacy in treatment and personal care;
- (2) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) working days. The Tennessee Department of Human Services, Adult Protective Services shall be notified immediately as required in T.C.A. § 71-6-103;

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

CHAPTER 1200-8-14  
PEDIATRIC TRAUMA CENTERS

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~~1200-8-14-.01 PURPOSE.~~ (Repeal.)

~~The Board recognizes that, although the overall instance of traumatic injury and death is less in the childhood age group than in the adult age groups, in many ways the development of an appropriate treatment scenario is more difficult in childhood injuries. Children are not "little adults". While it is recognized that the adult psychological response to trauma can be overwhelming, the injured child and his/her family present a much more complex environment for the trauma team. Since their acute cardiorespiratory response to trauma differs significantly from the adult, reacting to the critically injured child presents major problems to those who are only occasionally responsible for such patients.~~

~~Injured children present many problems over and above those relating to their injured parts. These include such diverse considerations as psychological management, problems of vascular access, administration of anesthesia, intensive care facilities specifically designed for children, as well as laboratory and support services similarly designed. The salvage of seriously injured children requires the services of physicians and nurses with specialized training in pediatric care, both surgical and medical. The nursing staff in particular must be educated and experienced in trauma nursing and the care, growth, and development of the pediatric patient. In most instances these resources are found in pediatric hospitals or hospitals with a significant pediatric commitment. Because of the special requirements for pediatric trauma, the Tennessee Board for Licensing of Health Care Facilities has developed these Pediatric trauma standards.~~

~~This Task Force, and hence the Board, recognized that trauma kills more children than all other deaths in this age group combined. In 1985, 3,709 children 15 years of age and under were killed in accidents involving motor vehicles, 934 of them five years and under. In Tennessee that year, of the 1,101 such fatalities, 99 were under the age of 15 and another 167 were ages 16 to 20, or, as with the national average, one in four of all such deaths. National statistics also show that for every pediatric trauma death there are 10 pediatric patients who will require pediatric trauma center care. Where systems of trauma care have been developed, deaths from accidental injury have decreased significantly in adults. However, only where pediatric trauma care systems have been developed has a similar decrease been shown in children.~~

~~*Authority:* T.C.A. §§68-11-201 through 68-11-205, 68-11-207 through 68-11-210, 68-11-213, 68-11-214, 68-11-216, 68-11-219 through 68-11-221, and 4-5-202. *Administrative History:* Original rule filed January 30, 1989; effective March 16, 1989.~~

~~1200-8-14-.02 DEFINITIONS.~~ (Repeal.)

- ~~(1) "Levels of Care" shall mean the type of trauma service provided by the institution as shown by the degree of commitment in personnel and facilities made to the delivery of that service.~~
- ~~(2) "Level I" shall designate that institution committed to providing optimal care for the acutely injured pediatric patient which meets all requirements in this regulation defined a Level of care I.~~
- ~~(3) "Level II" shall designate an institution committed to providing optimal care for the acutely injured pediatric patient that meets the requirements in this regulation defined as Level of care II.~~

(Rule 1200-8-14-.02, continued)

**Authority:** T.C.A. §§68-11-201 through 68-11-205, 68-11-207 through 68-11-210, 68-11-213, 68-11-214, 68-11-216, 68-11-219 through 68-11-221, and 4-5-202. **Administrative History:** Original rule filed January 30, 1989; effective March 16, 1989.

~~1200-8-14-.03 REQUIREMENTS.~~—(Repeal.)

(1) ~~Hospital Organization~~

~~There shall be demonstrated commitment by the hospital Board of Directors, administration, medical staff, and nursing staff to treat any pediatric patients presented to the facility for care.~~

~~The facility shall provide hospital emergency services to any applicant who applies for the same in case of injury or acute medical condition where the same is liable to cause death or severe injury or illness.~~

~~As specified in T.C.A. §68-39-302, the medical need of an applicant and the available medical resources of the facility, rather than the financial resources of an applicant, shall be the determining factors concerning the scope of service provided.~~

		LEVELS	
		I	II
<del>(a) LEVELS OF CARE</del>			
<del>1. Trauma Service/Team</del>			
		<del>X</del>	<del>X</del>
<del>2. Surgery Departments/Divisions/Services/ Sections (each staffed by qualified specialists).</del>			
	Cardiothoracic Surgery	<del>X</del>	<del>X<sup>1</sup></del>
	General Surgery	<del>X</del>	<del>X</del>
	Neurologic Surgery	<del>X</del>	<del>X</del>
	Gynecologic Surgery	<del>X</del>	<del>X</del>
	Ophthalmic Surgery	<del>X</del>	<del>X</del>
	Oral & Maxillofacial Surgery/Dentistry	<del>X</del>	<del>X</del>
	Orthopedic Surgery	<del>X</del>	<del>X</del>
	Otorhinolaryngologic Surgery	<del>X</del>	<del>X</del>
	Pediatric Surgery	<del>X</del>	<del>X<sup>2</sup></del>
	Plastic Surgery	<del>X</del>	<del>X</del>
	Urologic Surgery	<del>X</del>	<del>X</del>
<del>3. Non-surgical Departments/Divisions/ Services/Section (staffed by qualified specialists)</del>			
	Emergency Medicine	<del>X<sup>3</sup></del>	<del>X</del>
	Pediatrics	<del>X</del>	<del>X</del>
	Anesthesia	<del>X</del>	<del>X</del>
	Radiology	<del>X</del>	<del>X</del>
	Pathology	<del>X</del>	<del>X</del>

(Rule 1200-8-14-.03, continued)

LEVELS

I ————— II

4. — Surgical Specialties, in-house, 24 hours a day:

Pediatric Surgery	—————	X <sup>4</sup>
Neurologic Surgery	—————	X <sup>5</sup>

On-call and available from inside or outside the hospital:

Cardiothoracic Surgery	—————	X	—————	X <sup>1</sup>
General Surgery	—————		—————	X
Neurologic Surgery	—————		—————	X <sup>6</sup>
Microsurgery Capabilities	—————	X	—————	X <sup>7</sup>
Gynecologic Surgery	—————	X	—————	X
Hand Surgery	—————	X	—————	X <sup>8</sup>
Ophthalmic Surgery	—————	X	—————	X
Oral and Maxillofacial Surgery/ Dentistry	—————	X	—————	X
Orthopedic Surgery	—————	X	—————	X
Otorhinolaryngologic Surgery	—————	X	—————	X
Plastic Surgery	—————	X	—————	X
Urologic Surgery	—————	X	—————	X
Pedodontist	—————	X	—————	X

5. — Nonsurgical Specialties Availability, In-hospital, 24 hours a day:

Anesthesiology	—————	X <sup>9</sup>		
Pediatric Emergency Specialist	—————	X	—————	X <sup>10</sup>
Pediatric Intensivist	—————	X <sup>11</sup>		

On-call and available from inside or outside the hospital:

Anesthesiology	—————		—————	X
Cardiology	—————	X <sup>12</sup>	—————	X
Pulmonary Medicine	—————	X <sup>12</sup>	—————	X
Gastroenterology	—————	X <sup>12</sup>	—————	X
Hematology	—————	X <sup>12</sup>	—————	X
Infectious Disease	—————	X <sup>12</sup>	—————	X
Nephrology	—————	X <sup>12</sup>	—————	X
Neurology	—————	X <sup>12</sup>	—————	X
Pathology	—————	X <sup>13</sup>	—————	X <sup>13</sup>
Pediatrics	—————	X	—————	X
Psychiatry/Psychology	—————	X <sup>12</sup>	—————	X
Radiology	—————	X <sup>12</sup>	—————	X
Physical Medicine/Rehabilitation	—————	X <sup>12</sup>		

(Rule 1200-8-14-.03, continued)

~~(b) SPECIAL FACILITIES: RESOURCES/CAPABILITIES~~

~~1. Emergency Department~~

~~(i) Personnel~~

LEVELS

I \_\_\_\_\_ II

- ~~(I) Designated Physician Director (Boarded in Pediatrics with additional training or extensive expertise in Pediatrics Emergency Medicine or, boarded in Emergency Medicine with additional one (1) year training in Pediatric Emergency Medicine.~~

~~X \_\_\_\_\_ X<sup>14</sup>~~
- ~~(II) Physician with special competence in the care of the critically ill or injured child present in the E.D. 24 hours a day.~~

~~X<sup>15</sup> \_\_\_\_\_ X<sup>10</sup>~~
- ~~(III) E.D. staffed by full time (minimum of 100 hours/month) Is emergency physicians.~~

~~X<sup>15</sup> \_\_\_\_\_ X~~
- ~~(IV) Designated Nursing Supervisory position (full-time) to oversee pediatric emergency care.~~

~~X \_\_\_\_\_ X<sup>16</sup>~~
- ~~(V) All RN personnel assigned to the Pediatric Emergency Department component 24 hours a day will have special training in Pediatric Care and/or one (1) year pediatric Critical Care experience.~~

~~X \_\_\_\_\_ X<sup>17</sup>~~
- ~~(VI) Social Services and/or Child Life available in house or on call 24 hours a day.~~

~~X \_\_\_\_\_ X~~

(Rule 1200-8-14-.03, continued)

	LEVELS
	I ————— II
(ii) <del>Equipment</del>	
<del>Equipment for resuscitation and to provide support for the critically or seriously injured, appropriately sized for all ages, shall include but not be limited to:</del>	<del>X ————— X</del>
<del>(I) Communication equipment with EMS systems:</del>	<del>X ————— X</del>
<del>(II) Airway control and ventilation equipment laryngoscopes sizes 0, 1, 2, and 3 straight and curved:</del>	<del>X ————— X</del>
<del>I. laryngoscopes sizes 0, 1, 2, and 3 straight and curved:</del>	<del>X ————— X</del>
<del>II. Bag valve mask resuscitators, infant, child and adult.</del>	<del>X ————— X</del>
<del>III. Endotracheal tubes, cuffed and uncuffed, sized 2.5 to 9.0, sizes 2.5 to 6.0 uncuffed.</del>	<del>X ————— X</del>
<del>IV. Suction and appropriate sized catheters.</del>	<del>X ————— X</del>
<del>V. Airways</del>	<del>X ————— X</del>
<del>VI. Oxygen</del>	<del>X ————— X</del>
<del>VII. Tracheostomy and thoracostomy trays with tracheostomy tubes size 0 to 3 and chest tubes size 8 to 28 French.</del>	<del>X ————— X</del>
<del>(III) Cardiopulmonary monitors with infant and pediatric capability and at least two pressure capability.</del>	<del>X ————— X<sup>18</sup></del>
<del>(IV) Catheters for intravenous and intraarterial lines, (3 to 8 French, 16 to 24 gauge, intraosseous needles).</del>	<del>X ————— X</del>
<del>(V) Monitor defibrillator with adult and pediatric internal and external paddles, 0 to 400 watt/sec. capability.</del>	<del>X ————— X</del>

(Rule 1200-8-14-.03, continued)

	LEVELS
	I ————— II
(VI) <del>Trays for veinsection, suturing, plastics.</del>	<del>X ————— X</del>
(VII) <del>Pediatric splints, casts, traction, including equipment for cervical spine stabilization.</del>	<del>X ————— X</del>
(VIII) <del>NG tubes #10 to 18 French, 5 and 8 French feeding tubes.</del>	<del>X ————— X</del>
(IX) <del>Foley catheters, #8 through 14.</del>	<del>X ————— X</del>
(X) <del>Dialysis catheters.</del>	<del>X ————— X</del>
(XI) <del>Drugs, in pediatric concentrations.</del>	<del>X ————— X</del>
(XII) <del>IV solutions with both microdrip and high volume infusion sets.</del>	<del>X ————— X</del>
(XIII) <del>Pediatric LP and subdural trays</del>	<del>X ————— X</del>
(XIV) <del>Burr hole and ICP monitor trays.</del>	<del>X ————— X</del>
(XV) <del>Blood pressure cuffs for premie, infant, child, adult, thigh.</del>	<del>X ————— X</del>
(XVI) <del>Doppler for BP monitoring.</del>	<del>X ————— X</del>
(XVII) <del>Non-invasive blood pressure monitor.</del>	<del>X ————— X</del>
(XVIII) <del>Pulse oximeter.</del>	<del>X ————— X</del>
(XIX) <del>Pediatric anti-shock (MAST) trousers.</del>	<del>X ————— X</del>
(XX) <del>Infusion pumps with fractional cc. capability.</del>	<del>X ————— X</del>
(XXI) <del>Pediatric scales for weight measurement.</del>	<del>X ————— X</del>
(XXII) <del>Temperature control devices for patient, IV fluids and blood.</del>	<del>X ————— X</del>
 (iii) <del>Facility Design</del>	
 <del>Full time pediatric emergency area with a designated area for the resuscitation and stabilization of pediatric trauma patients; equipped for neonatal, pediatric/adolescent patients and of adequate size to accommodate a full resuscitation team.</del>	 <del>X ————— X</del>

(Rule 1200-8-14-.03, continued)

(2) ~~PEDIATRIC INTENSIVE CARE UNIT~~

~~For Level 11 centers, a current signed transfer agreement with a hospital with a Pediatric Intensive Care Unit should be appropriately utilized. An adult intensive care unit will not suffice for the care of critically injured pediatric patients.~~

LEVELS

I ————— II

(a) ~~Personnel~~

- |  |                         |
|--|-------------------------|
| 1. <del>Designated Medical Director, Boarded in Pediatrics, and Board certified/eligible for pediatric critical care.</del>  | X ————— X               |
| 2. <del>Physician on duty in hospital 24 hours a day.</del>  | X <sup>11</sup> ————— X |
| 3. <del>Designated nursing unit management (full-time pediatric).</del>  | X ————— X               |
| 4. <del>RN to patient ratio, depending on acuity should not exceed 1:3 on each shift. RN's shall have special competence in pediatric critical care and special training in pediatric trauma care.</del> | X ————— X               |
| 5. <del>Support services from respiratory therapy, pharmacy, lab, x-ray, and blood bank available 24 hours a day.</del>  | X ————— X               |
| 6. <del>A designated nurse educator shall be identified for the critical care unit.</del>  | X <sup>20</sup> ————— X |
| 7. <del>Distinct physical facility.</del>  | X ————— X               |
| (i) <del>may house medical or surgical patients.</del>   | X ————— X               |
| (ii) <del>isolation capacity.</del>  | X ————— X               |
| (iii) <del>defined bed requirements.</del>   | X ————— X               |

- minimum 75 sq. ft./bed site
- 11 electrical outlets per bed\*
- 2 oxygen outlets/bed
- 1 compressed air outlet per bed
- 2 vacuum outlets/bed
- 6 grounding sockets/bed
- \* — on backup emergency generator

(Rule 1200-8-14-.03, continued)

	LEVELS	
	I	II
(iv) <del>Monitoring equipment capability for continuous monitoring of:</del>		
(I) <del>ECG/heart rate</del>	<del>X</del>	<del>X</del>
(II) <del>Respirations</del>	<del>X</del>	<del>X</del>
(III) <del>Temperature</del>	<del>X</del>	<del>X</del>
(IV) <del>Central Venous Pressure</del>	<del>X</del>	<del>X</del>
(V) <del>Pulmonary arterial pressure</del>	<del>X</del>	<del>X</del>
(VI) <del>Intracranial pressure</del>	<del>X</del>	<del>X</del>
(VII) <del>3 simultaneous pressure capability</del>	<del>X</del>	<del>X</del>
(VIII) <del>Non-invasive blood pressure</del>	<del>X</del>	<del>X</del>
(IX) <del>Pulse oximeter</del>	<del>X</del>	<del>X</del>
(X) <del>End-tidal PCO2</del>	<del>X</del>	<del>X</del>
(XI) <del>Pulmonary function tests</del>	<del>X</del>	<del>X</del>
(XII) <del>Equipment Characteristics</del>	<del>X</del>	<del>X</del>
I. <del>high/low alarms for heart rate, respirations, and all pressures,</del>		
<del>- visible</del>	<del>X</del>	<del>X</del>
<del>- audible</del>	<del>X</del>	<del>X</del>
II. <del>electrical patient isolation</del>	<del>X</del>	<del>X</del>
III. <del>routine testing and maintenance</del>	<del>X</del>	<del>X</del>
8. <del>Portable Equipment</del>		
(i) <del>Beds, cribs, isolets</del>	<del>X</del>	<del>X</del>
(ii) <del>Oxygen source</del>	<del>X</del>	<del>X</del>
(iii) <del>Oxygen analyzers</del>	<del>X</del>	<del>X</del>
(iv) <del>Air oxygen blenders</del>	<del>X</del>	<del>X</del>
(v) <del>Humidifiers</del>	<del>X</del>	<del>X</del>
(vi) <del>Compressors</del>	<del>X</del>	<del>X</del>
(vii) <del>Respirators</del>	<del>X</del>	<del>X</del>
(viii) <del>Emergency cart</del>	<del>X</del>	<del>X</del>
(ix) <del>Defibrillator with pediatric paddles</del>	<del>X</del>	<del>X</del>
(x) <del>Suction machine</del>	<del>X</del>	<del>X</del>
(xi) <del>Doppler BP device</del>	<del>X</del>	<del>X</del>
(xii) <del>Pacemaker capability</del>	<del>X</del>	<del>X</del>
(xiv) <del>Infusion pumps with micro capability</del>	<del>X</del>	<del>X</del>
(xv) <del>Heating/cooling blankets</del>	<del>X</del>	<del>X</del>
(xvi) <del>Spot light</del>	<del>X</del>	<del>X</del>
(xvii) <del>Otoscope/ophthalmoscope</del>	<del>X</del>	<del>X</del>
(xviii) <del>Refractometer</del>	<del>X</del>	<del>X</del>
(xix) <del>Pediatric laryngoscope/bronchoscope</del>	<del>X</del>	<del>X</del>
(xx) <del>Airway control and ventilation equipment</del>	<del>X</del>	<del>X</del>
(I) <del>laryngoscopes sizes 0, 1, 2, and 3, straight and curved blades.</del>		

(Rule 1200-8-14-.03, continued)

(II) <del>bag-valve mask resuscitators, infant, child, adult</del>	
(III) <del>endotracheal tubes.</del>	
(IV) <del>suction catheters.</del>	
(V) <del>airways.</del>	
	<b>LEVELS</b>
	I ————— II
(VI) <del>tracheostomy tray with tracheostomy tubes sizes 0 to 3.</del>	X ————— X
(VII) <del>thoracotomy tray with chest tubes (10 to 28 French) and pericardiocentesis capability.</del>	X ————— X
(xxi) <del>Scales</del>	X ————— X
9. <del>Small equipment</del>	
(i) <del>Emergent and non-emergent drugs in pediatric concentrations.</del>	X ————— X
(ii) <del>Catheters for intravenous and intraarterial lines (3 to 8 French and 16 to 24 gauge) and intraosseous needles.</del>	X ————— X
(iii) <del>Venous and arterial cutdown trays.</del>	X ————— X
(iv) <del>Pediatric LP and subdural trays.</del>	X ————— X
(v) <del>ICP monitor tray.</del>	X ————— X
(vi) <del>Pediatric splints and traction equipment.</del>	X ————— X
(vii) <del>Foley catheters (8 to 14 in size).</del>	X ————— X
(viii) <del>NG tubes (#10 to 18 French and #3 and 5 feeding tubes).</del>	X ————— X
(ix) <del>Dialysis catheters.</del>	X ————— X
(x) <del>Isolation materials.</del>	X ————— X
10. <del>Nursing Education</del>	X ————— X

(Rule 1200-8-14-.03, continued)

(3) ~~POST ANESTHETIC RECOVERY ROOM (PAR)~~

LEVELS

I ————— II

(a) ~~Personnel~~

- |  |           |
|--|-----------|
| 1. <del>Registered nurses and other essential personnel on call 24 hours a day.</del>  | X ————— X |
| 2. <del>Registered nurses caring for post anesthetic patients must be competent in the post anesthesia care of the pediatric trauma patient.</del> | X ————— X |

(b) ~~Equipment~~

- |   |           |
|---|-----------|
| 1. <del>Airway control and ventilation equipment. Laryngoscopes, assorted blades, airways, endotracheal tubes, bag-mask resuscitators of all sizes.</del> | X ————— X |
| 2. <del>Oxygen, air and suction devices.</del>  | X ————— X |
| 3. <del>Electrocardiographic pressure and intracranial pressure monitoring apparatus.</del>   | X ————— X |
| 4. <del>Thermal control equipment:</del><br><del>- Radiant warmer</del><br><del>- Blood warmer</del>  | X ————— X |
| 5. <del>Resuscitation cart containing emergency drugs and including pediatric drug dosage chart.</del>  | X ————— X |
| 6. <del>Immediate access to sterile surgical supplies for emergency procedures including thoracostomy, thoracotomy, tracheostomy, and venesection.</del>  | X ————— X |

(4) ~~ACUTE HEMODIALYSIS CAPABILITY~~

- |  |                         |
|--|-------------------------|
| (a) <del>Registered nurses in house or on call 24 hours a day, trained in hemodialysis of the pediatric patient.</del> | X ————— X <sup>21</sup> |
| (b) <del>Appropriate equipment for pediatric hemodialysis.</del>   | X ————— X <sup>21</sup> |

(5) ~~ORGANIZED BURN CARE~~

<del>Physician directed Burn Center/Unit staffed by nursing personnel trained in burn care and equipped properly for pediatric patients.</del>	X <sup>22</sup> ————— X <sup>22</sup>
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(Rule 1200-8-14-.03, continued)

	LEVELS
	I ————— II
<del>(6) SPINAL CORD INJURY MANAGEMENT CAPABILITY</del>	<del>X<sup>23</sup> ————— X<sup>23</sup></del>
<del>(7) RADIOLOGIC SPECIAL CAPABILITIES 24 HOURS A DAY</del>	<del>X ————— X</del>
<del>(a) Angiography</del>	
<del>(b) Computed tomography</del>	
<del>(8) SOCIAL SERVICE CAPABILITIES AVAILABLE, ON CALL 24 HOURS A DAY</del>	<del>X ————— X</del>
<del>(9) CHILD LIFE CAPABILITIES INCLUDING SPIRITUAL COUNSELING</del>	<del>X</del>
<del>(10) GENERAL PEDIATRIC MEDICAL / SURGICAL NURSING UNIT</del>	
<del>(a) Personnel</del>	
<del>1. Pediatric nursing staff with special training in pediatric trauma care.</del>	<del>X ————— X</del>
<del>2. Unit Nursing Administrator.</del>	<del>X ————— X</del>
<del>3. Unit Nurse Educator</del>	<del>X ————— X</del>
<del>(b) Equipment</del>	
<del>Equipment to provide support and resuscitation of the injured neonate, pediatric/adolescent patient should be readily available and shall include but not be limited to:</del>	
<del>1. Airway control and ventilation equipment including laryngoscopes, assorted blades, airways, endotracheal tubes, and bag-mask resuscitators of all sizes. (This equipment must be immediately available).</del>	<del>X ————— X</del>
<del>2. Oxygen, air, suction devices.</del>	<del>X ————— X</del>

(Rule 1200-8-14-.03, continued)

LEVELS

	I	II
3. <del>Electrocardiograph, monitor and defibrillator, to include internal and external paddles.</del>	<del>X</del>	<del>X</del>
4. <del>All standard intravenous fluids and administration devices, including IV catheters designed with the capacity for delivering IV fluids and medications at rates and amounts appropriate for children ranging in age from neonate to adolescent.</del>	<del>X</del>	<del>X</del>
5. <del>Drugs and supplies necessary for emergency care.</del>	<del>X</del>	<del>X</del>
6. <del>Thoracotomy tube sets, cut-down trays.</del>	<del>X</del>	<del>X</del>

(11) ~~PEDIATRIC TRAUMA TEAM/SERVICE~~

~~The hospital shall establish within its organization a defined Pediatric Trauma Service for the injured child (see Standard I, "Hospital Organization").~~

(a) <del>The Pediatric Trauma Program Director shall be a Pediatric Surgeon, certified "or eligible for certification", in Pediatric Surgery with demonstrated special competence in care of the injured child. The Director shall have full responsibility and authority for the Trauma Service.</del>	<del>X</del>	<del>X</del>
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(b) ~~Pediatric Trauma Nurse Coordinator~~

<del>Pediatric Trauma Nurse Coordinator</del>	<del>X<sup>25</sup></del>	
<del>Pediatric Nurse Coordinator</del>	<del>_____</del>	<del>X<sup>26</sup></del>

(c) ~~Trauma Team members requiring immediate availability:~~

1. <del>Pediatric surgeon/Trauma Service Director or his/her designee.</del>	<del>X<sup>27</sup></del>	<del>X<sup>28</sup></del>
2. <del>Pediatric emergency physician or his/her designee.</del>	<del>X</del>	<del>X<sup>10</sup></del>
3. <del>Anesthesiologist</del>	<del>X<sup>9</sup></del>	
4. <del>Neurologic surgeon</del>	<del>X<sup>5</sup></del>	
5. <del>Two Pediatric emergency department R.N.'s</del>	<del>X</del>	<del>X<sup>29</sup></del>
6. <del>Respiratory therapist</del>	<del>X</del>	<del>X</del>
7. <del>Laboratory technician</del>	<del>X</del>	<del>X</del>

(Rule 1200-8-14-.03, continued)

	LEVELS	
	I	II
8. Radiology technician	X	X
<del>(d) Trauma Team members on call (30 minutes or less response time):</del>		
1. Anesthesiologist		X
2. Neurologic Surgeon		X
3. Orthopedic Surgeon	X	X
4. Cardiothoracic Surgeon	X	X <sup>1</sup>
<del>5. Support personnel on call (within 30 minutes) inside or outside of the hospital:</del>		
(i) Chaplain	X	X
(ii) Social Worker	X	X
(iii) Child Protection Team	X	X
(iv) Sexual Abuse Team	X	X
<del>(e) Support Services On Call in Hospital for Trauma Team Services:</del>		
1. 24 hour laboratory With micro capabilities and blood gasanalysis capabilities, and blood bank capabilities.	X	X
2. 24 hour X-ray capabilities		
(i) Ultrasound	X	X
(ii) C.T.	X	X
(iii) Angiography	X	X
3. 24 hour Respiratory therapy capabilities with personnel with special competence in pediatric care and equipment.	X	X

~~(12) PEDIATRIC TRAUMA COMMITTEE~~

~~May be a subcommittee of the hospital's Critical Care Committee, and is responsible for developing, auditing and maintaining trauma protocols for quality assurance. All disciplines involved in the care of the injured child are responsible for being intimately familiar with these protocols.~~

~~X~~ ————— ~~X~~<sup>21</sup>

~~This committee is chaired by the Director of the Pediatric Trauma Program and is to have representatives from each of the following:~~

(Rule 1200-8-14-.03, continued)

LEVELS

I ————— II

- ~~(a) Pediatric Surgery~~
- ~~(b) Pediatric Emergency Department~~
- ~~(c) Pediatric Intensive Care~~
- ~~(d) Neurosurgery~~
- ~~(e) Anesthesia~~
- ~~(f) Radiology~~
- ~~(g) Orthopedics~~
- ~~(h) Pathology~~
- ~~(i) Respiratory Therapy~~
- ~~(j) Nursing (usually the Pediatric Trauma Nurse Coordinator and head nurse) or their designee from the Pediatric Emergency Department, Pediatric Intensive Care Unit, and Pediatric regular post-surgical/trauma floor(s).~~
- ~~(k) Rehabilitation Therapy~~

~~(13) PEDIATRIC TRAUMA REGISTRY~~

~~There shall be a Pediatric Trauma Registry developed or adopted, and maintained, to include but not be limited to auditing of:~~

~~X ————— X~~

- ~~(a) Severity of injury (including a "Trauma score").~~
- ~~(b) Anatomic site of injury.~~
- ~~(c) Nature of injury.~~
- ~~(d) Mechanism of injury.~~
- ~~(e) Classification of injury.~~
- ~~(f) Demographic information (e.g., age, sex, race, etc.).~~
- ~~(g) Outcome.~~
- ~~(h) Transport Particulars.~~

~~(14) OPERATING SUITE: SPECIAL REQUIREMENTS~~

~~The operating suite in both Level I and Level II shall be staffed and equipped to handle all children who are present in the Emergency Department and are in need of immediate surgical intervention. Equipment and supplies must be appropriate for care of the pediatric trauma patient ranging in age from neonate to adolescent.~~

- ~~(a) An operating room dedicated to trauma service shall be adequately staffed with personnel IMMEDIATELY AVAILABLE "in house" 24 hours a day.~~
- ~~(b) A second operating room shall be available and staffed within 30 minutes. When the first team is in surgery, the second call team will be alerted and available within 30 minutes.~~
- ~~(c) At least one registered nurse must be physically present in the operating room.~~

~~X ————— X<sup>32</sup>~~

~~X ————— X~~

~~X ————— X~~

(Rule 1200-8-14-.03, continued)

	LEVELS	
	I	II
(d) <del>Equipment</del>		
1. <del>Cardiopulmonary bypass capability.</del>	<del>X</del>	
2. <del>Operating microscope</del>	<del>X</del>	<del>X7</del>
3. <del>Thermal control equipment</del>	<del>X</del>	<del>X</del>
<del>for patient, i.e., radiant warmers</del>		
<del>for parenteral fluids</del>		
<del>for blood</del>		
<del>for environment, i.e., thermostatic room temperature control.</del>		
4. <del>X ray capability, including C arm</del>	<del>X</del>	<del>X</del>
5. <del>Endoscopes, all varieties</del>	<del>X</del>	<del>X</del>
6. <del>Craniotomy equipment, including intracranial pressure monitoring equipment.</del>	<del>X</del>	<del>X</del>
7. <del>Invasive and noninvasive monitoring equipment to include electrocardiographic, temperature, continuous pressure and pulse oximetry.</del>		
8. <del>Pediatric anesthesia equipment. Pediatric ventilation equipment and the ability to monitor administered oxygen concentration.</del>	<del>X</del>	<del>X</del>
9. <del>Airway control equipment including laryngoscopes, assorted blades, airways, endotracheal tubes, bag-mask resuscitators of all sizes. Oxygen, air, and suction devices.</del>	<del>X</del>	<del>X</del>
10. <del>Defibrillator, monitor, including internal and external paddles.</del>	<del>X</del>	<del>X</del>
11. <del>Instrumentation, i.e., blood pressure cuffs, chest tubes, nasogastric tubes, and urinary drainage apparatus specific to the pediatric patient ranging in age from neonate to adolescent.</del>	<del>X</del>	<del>X</del>
12. <del>Laparotomy tray</del>	<del>X</del>	<del>X</del>
13. <del>Thoracotomy tray and chest retractors of appropriate size.</del>	<del>X</del>	<del>X</del>
14. <del>Synthetic grafts of all sizes.</del>	<del>X</del>	<del>X</del>

(Rule 1200-8-14-.03, continued)

	LEVELS	
	I	II
15. <del>Spinal immobilization and neck immobilization equipment.</del>	<del>X</del>	<del>X</del>
16. <del>Fracture table with Pediatric capability.</del>	<del>X</del>	<del>X</del>
17. <del>Auto transfusion with Pediatric capability.</del>	<del>X</del>	<del>X</del>
18. <del>Pediatric drug dosage chart.</del>	<del>X</del>	<del>X</del>
19. <del>Tracheostomy tubes, neonatal through adolescent.</del>	<del>X</del>	<del>X</del>
(e) <del>Comprehensive toxicological screening</del>		
<del>(15) CLINICAL LABORATORIES SERVICES AVAILABLE 24 HOURS A DAY</del>		
(a) <del>24 hour microcapabilities</del>	<del>X</del>	<del>X</del>
(b) <del>Standard analysis of blood, urine, and other body fluids</del>	<del>X</del>	<del>X</del>
(c) <del>Blood typing and cross matching</del>	<del>X</del>	<del>X</del>
(d) <del>Coagulation studies</del>	<del>X</del>	<del>X</del>
(e) <del>Blood Bank and access to a community central blood bank and hospital storage facilities</del>	<del>X</del>	<del>X</del>
(f) <del>Blood gases and pH determinations</del>	<del>X</del>	<del>X</del>
(g) <del>Microbiology</del>	<del>X</del>	<del>X</del>
(h) <del>Comprehensive toxicological screening</del>	<del>X</del>	<del>X</del>
<del>(16) TRAUMA RESEARCH PROGRAM</del>		
<del>Trauma Research Program</del>	<del>X</del>	<del>X</del>
<del>(17) TRAUMA TRAINING PROGRAMS</del>		
<del>Training Programs in Continuing Education Provided By and For:</del>		

(Rule 1200-8-14-.03, continued)

	LEVELS	
	I	II
(a) Staff Physicians	X	X
(b) Nurses	X	X
(c) Allied health personnel	X	X
(d) Community physicians	X	X
(e) Prehospital providers (local and regional)	X	X

~~(18) TRAUMA REHABILITATION PROGRAM~~

~~Rehabilitation Services with a special competence in the care of pediatric patients:~~

<del>(a) Physical Therapy</del>	<del>X</del>	<del>X</del>
<del>(b) Occupational Therapy</del>	<del>X</del>	
<del>(c) Speech Therapy</del>	<del>X</del>	
<del>(d) Special Education</del>	<del>X</del>	<del>X</del>

~~(19) ORGAN DONATION~~

~~Organ Donation protocol—Each center must have an organized protocol with a transplant team or service to identify possible organ donors and assist in procuring for donation, consistent with federal law.~~

~~X~~ — ~~X~~

~~(20) TRANSPORT CAPABILITIES~~

~~(a) Active Participation in a Transport Program, air and ground, for critically injured pediatric patients.~~

~~X~~ — ~~X~~

~~(b) Helipad or Helicopter Landing Area~~

~~X~~ — ~~X~~

~~(21) HOME HEALTH SERVICES~~

~~Home Health Services~~

~~(Requirement may be met by a contractual arrangement with an agency to provide home health services).~~

~~X~~ — ~~X~~

*FOOTNOTES*

~~1. Or substituted by a current signed transfer agreement with an institution with Cardiothoracic Surgery and Cardio-Pulmonary bypass capability.~~

~~2. Or substituted by a current signed transfer agreement with a hospital having a pediatric surgical service. A general surgeon with a particular interest in pediatric surgery should be present at the Level II center.~~

~~3. A defined administrative component of Pediatric Emergency Medicine.~~

(Rule 1200-8-14-.03, continued)

- ~~4. This requirement may be fulfilled by senior surgical residents (greater than or equal to PGY4) who have special competence, as designated by the Chief of Surgery, in the assessment and treatment of emergency situations in children. When these personnel are used to fulfill this requirement, staff pediatric surgical specialists shall be promptly available within 30 minutes. In the temporary absence of the Pediatric Surgeon this requirement may be fulfilled by a General Surgeon with additional training and/or experience in pediatric surgery as designated by the Pediatric Surgeon.~~
- ~~5. This requirement may be fulfilled by a neurosurgical resident who has special competence, as judged by the Chief of Neurosurgery, in the care of patients with neurosurgical emergencies, and who is capable of assessing emergent conditions and initiating treatment in the injured child. A staff specialist in Neurosurgery must be promptly available within 30 minutes. This requirement can be met by an attending surgeon and/or (greater than or equal to PG Y4) surgical resident.~~
- ~~6. Thirty (30) minutes response time.~~
- ~~7. Or substituted by current signed transfer agreement with an institution with Microsurgery capability.~~
- ~~8. Or substituted by current signed transfer agreement with an institution with Hand surgery capability.~~
- ~~9. Requirement may be fulfilled by an anesthesia (PG Y3) resident capable of assessing emergency situations and initiating proper treatment or a CRNA as credited by the Chief of Anesthesiology. A staff anesthesiologist must be promptly available within thirty (30) minutes.~~
- ~~10. Requirement may be met by an Emergency Medicine Physician with competence in management of the pediatric patient. Requires a physician with training in pediatrics such as elective pediatric emergency department continuing education courses or completing the advance pediatric life support course.~~
- ~~11. Requirements may be fulfilled by attending level pediatricians or pediatric residents (PG Y2 or above) designated by the PICU Director as capable of assessing and treating emergency conditions in pediatric patients. When residents are used to fulfill this requirement, the staff specialist in Pediatric Critical Care Medicine shall be promptly available within thirty (30) minutes. This requirement shall be provided in addition to the Pediatric Emergency attendant in the emergency department.~~
- ~~12. All medical specialists should have pediatric expertise as evidenced by Board Certification, Fellowship training, or demonstrated commitment and continuing medical education in their subspecialty area.~~
- ~~13. Forensic pathologist must be available either as part of the hospital staff or on a consulting basis.~~
- ~~14. Requirement may be met by a full time Emergency Medicine physician with extensive experience in pediatric care and with a Pediatric consultant readily available.~~
- ~~15. Requires a specialist in Pediatric Emergency Medicine. This individual must be (a) Board eligible or certified in Pediatrics, OR (b) Board prepared or certified in Emergency Medicine with formal training (a minimum of one (1) year) in Pediatric Emergency Medicine, AND, (c) spending a minimum of 100 hours in the delivery of emergency care to the pediatric patient per month.~~
- ~~16. The requirement may be met by a nurse designated as responsible for providing pediatric expertise to the Emergency Department.~~
- ~~17. Requirement may be met by having at least one (1) such qualified RN per shift.~~
- ~~18. Requirement may be met by having one such monitor with infant and pediatric capability.~~
- ~~19. Requirement may be met by having a specified area for the pediatric resuscitation and stabilization.~~

(Rule 1200-8-14-.03, continued)

- ~~20. An advanced pediatric life support course and a Nurse Trauma course designed by the Director of the Trauma Team will be available to all PICU nursing staff.~~
- ~~21. Or substituted by a current signed transfer agreement with a hospital having hemodialysis capabilities.~~
- ~~22. Or substituted by a current signed transfer agreement with a Burn Center or hospital with a Burn Center.~~
- ~~23. In circumstances where a designated spinal cord injury rehabilitation center exists in the region which is equipped with personnel and facilities specific for children, early transfer should be considered. Formal written transfer agreements should be in effect.~~
- ~~24. Requirement may be met by a General Surgeon with additional training and/or experience in pediatric surgery.~~
- ~~25. Responsible for QA, nursing education and other operational issues.~~
- ~~26. Responsible for coordination of levels of pediatric trauma activity including QA.~~
- ~~27. This requirement may be fulfilled by senior surgical residents (greater than or equal to PG Y4) who have special competence, as designated by the Chief of Surgery, in the assessment and treatment of emergency situations in children. When these personnel are used to fulfill this requirement, staff pediatric surgical specialists shall be promptly available within 30 minutes.~~
- ~~28. Requirement may be met by a General Surgeon with additional training and/or experience in pediatric surgery, thirty (30) minutes or less from the hospital.~~
- ~~29. This requirement may be met by general emergency department RN's.~~
- ~~30. Requirement may be met by having at least one therapist on each shift with pediatric experience and/or education.~~
- ~~31. This requirement may be met by the hospital's Trauma Committee.~~
- ~~32. Nursing staff may be available on call.~~
- ~~33. Pediatric Trauma Standards Interpretations developed by the Board.~~

**Authority:** T.C.A. §§68-11-201 through 68-11-205, 68-11-207 through 68-11-210, 68-11-213, 68-1-214, 6-1-216, 68-11-219 through 68-11-221, and 4-5-202. **Administrative History:** Original rule filed January 30, 1989; effective March 16, 1989.

**~~1200-8-14-.04 PROGRAMS FOR QUALITY ASSURANCE. (Repeal.)~~**

- ~~(1) Special audit for trauma deaths.~~
- ~~(a) There shall be a review of ALL trauma related deaths.~~
- ~~(b) There must be a mechanism in place to review all deaths and identify those that are primary admitted patients versus secondary transferred patients. Those transferred must be further defined as:~~
- ~~1. transferred after treatment, i.e., airway and fluid management, or~~

(Rule 1200-8-14-.04, continued)

~~2. — direct admission after prolonged treatment which may have included surgery and was provided over several days at the primary receiving institution.~~

~~(2) — Morbidity and Mortality Review~~

~~(3) — Trauma Conference, Multidisciplinary~~

~~(a) — Regular and periodic multidisciplinary trauma conferences that include ALL members of the trauma team shall be held. This conference reviews the Quality Assurance through critiques of ALL individual cases. Optimally, this will be a weekly conference.~~

~~(b) — There must be documentation of:~~

- ~~1. — subject matter~~
- ~~2. — attendance~~

~~(c) — This conference should also include periodic review of:~~

- ~~1. — Morbidity and mortality.~~
- ~~2. — Mechanism of injury.~~
- ~~3. — Review of the emergency medical service locally and regionally.~~
- ~~4. — Specific case review.~~
- ~~5. — Trauma center/system review.~~
- ~~6. — Identification and solution of specific problems including organ procurement and donation.~~

~~(4) — The completed prehospital trip form must be included with the Medical Record.~~

~~(5) — Medical and Nursing quality assessment program, utilization review, and tissue review.~~

~~Documentation of Quality Assurance must include:~~

- ~~(a) — Problem identification~~
- ~~(b) — Analysis~~
- ~~(c) — Action plan~~
- ~~(d) — Documentation and location of action~~
- ~~(e) — Implementation~~
- ~~(f) — Reevaluation~~

*Authority:* T.C.A. §§68-11-201 through 6-11-205, 68-11-207 through 68-11-210, 68-11-213, 68-11-214, 68-11-216, 68-11-219 through 68-11-221, and 4-5-202. *Administrative History:* Original rule filed January 30, 1989; effective March 16, 1989.

**1200-8-14-.05 DESIGNATION PROCESS.**— (Repeal.)

~~(1) — Implementation of the designation process will be by the Licensing Board for Health Care Facilities. A site visit team will be responsible for making recommendations to this Board. Institutions wishing to be designated as Level I or Level II Trauma Centers will make application to the Board. If the application is considered to be insufficient, this fact will be communicated to the Institution. If the application is deemed to be sufficient and the Institution is visited by the Site Visit Team, the Team's findings will be discussed in an "Exit Interview" with representatives of the Institution. The Team's findings will also be documented and submitted to the Board. Designation will be effective for up to four (4) years.~~

~~(2) — The Site Visit Team will be advisory to the Board, and will consist of the following:~~

(Rule 1200-8-14-.05, continued)

- ~~(a) — Two physicians; one of whom will be a Pediatric Surgeon, another a Pediatric Intensivist or Pediatric Emergency Physician, one of whom will be from out of State.~~
- ~~(b) — A CEO of a Children's Hospital or a General Hospital with a Pediatric Trauma Program.~~
- ~~(c) — A Registered Nurse involved in Pediatric Emergency or Intensive Care.~~
  - ~~1. — These members will act as Consultants to the Board, and will be selected with the assistance of the TNA (Tennessee Nurses Association), the THA (\*Tennessee Hospital Association) and the state Committees on Trauma of the American College of Surgeons and the Tennessee Pediatric Society.~~
  - ~~2. — Interpretative guidelines adopted by the Board may be utilized as appropriate by the site team.~~
  - ~~3. — All costs of the application process, including costs of the site visit, will be borne by the applying institution.~~
  - ~~4. — Both Level I and Level II applications simultaneously will be considered and acted upon, so as to encourage establishment of a Pediatric Trauma System in each of the State's five regions.~~
- ~~(3) — VERIFICATION. Verification shall be biannual and based on submission to the Board of a written report by the Institution, summarizing information from the Institution's input to the Trauma Registry, Quality Assurance processes (to include outcome data), sponsored CME activities, Research activities, credentialing and CME participation of key Trauma Center personnel, current staffing and bedutilization data, and any revisions in the Pediatric Trauma Policies and Procedures implemented since the time of last site visit. Renewal of trauma center designation requires reapplication, including site visitation, every four (4) years.~~

*Authority:* T.C.A. §§68-11-201 through 68-11-205, 68-11-207 through 68-11-210, 68-11-213, 68-11-214, 68-11-216, 68-11-219 through 68-11-221, and 4-5-202. *Administrative History:* Original rule filed January 30, 1989; effective March 16, 1989.

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

**CHAPTER 1200-8-27  
STANDARDS FOR HOMECARE ORGANIZATIONS  
PROVIDING HOSPICE SERVICES**

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**1200-8-27-.01 DEFINITIONS.**

- (1) Administrator. A person who:
  - (a) Is a licensed physician with at least one (1) year 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 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.
- (2) Adult. An individual who has capacity and is at least 18 years of age.
- (3) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.
- (4) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.
- (5) Agency. A Home Care Organization providing hospice services.
- (6) Bereavement Counselor. An individual who has at least a bachelor's degree in social work, counseling, psychology, pastoral care or specialized training or experience in bereavement theory and counseling.
- (7) Board. The Tennessee Board for Licensing Health Care Facilities.
- (8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(Rule 1200-8-27-.01, continued)

- (9) **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.
- (10) **Certified Master Social Worker.** A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.
- (11) **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.
- (12) **Commissioner.** The Commissioner of the Tennessee Department of Health or his or her authorized representative.
- (13) **Competent.** A patient who has capacity.
- (14) **Core Services.** Services consisting of nursing, medical social services, physician services and counseling services.
- (15) **Corrective Action Plan/Report.** A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:
  - (a) the action(s) implemented to prevent the reoccurrence of the unusual event,
  - (b) the time frames for the action(s) to be implemented,
  - (c) the person(s) designated to implement and monitor the action(s), and
  - (d) the strategies for the measurements of effectiveness to be established.
- (16) **Department.** The Tennessee Department of Health.
- (17) **Designated Physician.** A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.
- (18) **Do Not Resuscitate (DNR) Order.** An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.
- (19) **Emancipated Minor.** Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.
- (20) **Emergency Responder.** A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(Rule 1200-8-27-.01, continued)

- (21) **Guardian.** A judicially appointed guardian or conservator having authority to make a health care decision for an individual.
- (22) **Hazardous Waste.** Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.
- (23) **Health Care.** Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).
- (24) **Health Care Decision.** Consent, refusal of consent or withdrawal of consent to health care.
- (25) **Health Care Decision-maker.** In the case of a patient who lacks 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 guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-8-27-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.
- (26) **Health Care Institution.** A health care institution as defined in T.C.A. § 68-11-1602.
- (27) **Health Care Provider.** A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.
- (28) **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.
- (29) **Home Health Aide/Hospice Aide.** A person who has completed a total of seventy-five (75) hours of training which included sixteen (16) hours of clinical training prior to or during the first three (3) months of employment and who is qualified to provide basic services, including simple procedures as an extension of therapy services, personal care regarding nutritional needs, ambulation and exercise, and household services essential to health care at home.
- (30) **Homemaker Service.** A non-skilled service in the home to maintain independent living which does not require a physician's order. An agency does not have to be licensed as a home care organization to provide such services.
- ~~(31) **Hospice Services.** As defined by T.C.A. § 68-11-201, "hospice services" means a coordinated program of care, under the direction of an identifiable hospice administrator, providing palliative and supportive medical and other services to hospice patients and their families in the patient's regular or temporary place of residence. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week. (Delete.)~~
- (31) **Hospice Services.** As defined by T.C.A. § 68-11-201, "hospice services" means a coordinated program of care, under the direction of an identifiable hospice administrator, providing palliative and supportive medical and other services to hospice patients and their families in the patient's regular or temporary place of residence. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week. "Hospice services" may also be provided to a non-hospice patient limited to palliative care only.
- (32) **Incompetent.** A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(Rule 1200-8-27-.01, continued)

- (33) Individual instruction. An individual's direction concerning a health care decision for the individual.
- (34) 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.
- (35) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.
- (36) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.
- (38) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (39) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries and other written electronic or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to patients.
- (40) Medical Social Services. Medical social services must be provided by a qualified social worker under the direction of a physician, in accordance with the plan of care.
- (41) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.
- (42) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (43) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (44) Palliative. The reduction or abatement of pain or troubling symptoms, by appropriate coordination of all elements of the hospice care team, to achieve needed relief of distress.
- ~~(45) Patient. Hospice patient means only a person who has been diagnosed as terminally ill; been certified by a physician in writing to have an anticipated life expectancy of six (6) months or less; has voluntarily through self or a surrogate requested admission to a hospice; and been accepted by a licensed hospice. (Delete.)~~
- (45) Patient. Hospice patient means only a person who has been diagnosed as terminally ill; been certified by a physician in writing to have an anticipated life expectancy of six (6) months or less; has voluntarily through self or a surrogate requested admission to a hospice; and been accepted by a licensed hospice. Patient will also include non-hospice patient receiving only palliative care.
- (46) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; 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

(Rule 1200-8-27-.01, continued)

- care would conflict with the terms of such living will shall not be deemed “patient abuse” for purposes of these rules.
- (47) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
  - (48) Personally Informing. A communication by any effective means from the patient directly to a health care provider.
  - (49) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
  - (50) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
  - (51) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.
  - (52) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.
  - (53) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.
  - (54) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient’s health care needs. Such availability shall include, but not be limited to, availability by telephone.
  - (55) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
  - (56) Respiratory Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.
  - (57) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.
  - (58) Respite Care. A short-term period of inpatient care provided to the patient only when necessary to relieve the family members or other persons caring for the patient.
  - (59) Shall or Must. Compliance is mandatory.
  - (60) Social Work Assistant. A person who has a baccalaureate degree in social work, psychology, sociology or other field related to social work, and has at least one (1) year of social work experience in a health care setting. Social work related fields include bachelor/masters degrees in psychology, sociology, human services (behavioral sciences, not human resources), masters degree in counseling fields (psychological guidance and guidance counseling) and degrees in gerontology.
  - (61) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.
  - (62) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that religious organization.

(Rule 1200-8-27-.01, continued)

- (63) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (64) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.
- (65) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (66) 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.
- (67) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (68) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.
- (69) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
- (70) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.
- (71) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.
- (72) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.
- (73) Volunteer. An individual who agrees to provide services to a hospice care patient and/or family member(s), without monetary compensation, in either direct patient care or an administrative role and supervised by an appropriate hospice care employee.

**Authority:** T.C.A. §§4-5-202, 4-5-204, 39-11-106, 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, and 68-11-1802. **Administrative History:** Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.

#### **1200-8-27-.02 LICENSING PROCEDURES.**

- (1) No person, partnership, association, corporation or any 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 Hospice Services 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 and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the agency shall not be changed without first notifying the Department in

(Rule 1200-8-27-.05, continued)

*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, 68-11-222 and 71-6-121. *Administrative History:* Original filed April 25, 1996; effective July 9, 1996. Repeal and new rule filed April 17, 2000; effective July 1, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007.

**1200-8-27-.05 ADMISSIONS, DISCHARGES AND TRANSFERS.**

- (1) The hospice service program shall have a policy to admit only patients who meet the following criteria:
  - (a) Has been diagnosed as terminally ill;
  - (b) Has been certified by a physician, in writing, to have an anticipated life expectancy of six (6) months or less;
  - (c) Has personally or through a representative voluntarily requested admission to, and been accepted by, a licensed hospice service organization; and
  - ~~(d) Has personally or through a representative, in writing, given informed consent to receive hospice care. (Delete.)~~
  - (d) Has personally or through a representative, in writing, given informed consent to receive hospice care; or
  - (e) Is a non-hospice patient that has been determined to need palliative care only.
- (2) Patients shall be accepted to receive hospice services on the basis of a reasonable expectation that the patient's medical, nursing and psychosocial needs can be met adequately by the organization in the patient's regular or temporary place of residence.
- (3) Care shall follow a written plan of care established and reviewed by the attending physician, the medical director or physician designee and the interdisciplinary group prior to providing care. Care shall continue under the supervision of the attending physician.
- (4) The agency staff shall determine if the patient's needs can be met by the organization's services and capabilities.
- (5) Every person admitted for care or treatment to any agency covered by these rules shall be under the supervision of a physician as defined in this chapter who holds a license in good standing. The name of the patient's attending physician shall be recorded in the patient's medical record.
- (6) The agency staff shall obtain the patient's written consent for hospice services.
- (7) The signed consent form shall be included with the patient's individual clinical record.
- (8) A diagnosis must be entered in the admission records of the agency for every person admitted for care or treatment.
- (9) No medication or treatment shall be provided to any patient of an agency except on the order of a physician or dentist lawfully authorized to give such an order.
- (10) A medical record shall be developed and maintained for each patient admitted.

(Rule 1200-8-27-.05, continued)

- (11) No patient shall be involuntarily discharged without a written order from the attending physician or the medical director stating the patient does not meet hospice criteria, or through other legal processes, and timely notification of next of kin and/or the authorized representative.
- (12) When a patient is discharged, a summary of the significant findings and events of the patient's care, the patient's condition on discharge and the recommendation and arrangement for future care, if any, is required.
- (13) 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 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 April 17, 2000; effective July 1, 2000.

**1200-8-27-.06 BASIC AGENCY FUNCTIONS.**

- (1) An organization providing hospice services must ensure that substantially all core services are routinely provided directly by hospice employees. A hospice service program may use contracted staff if necessary to supplement hospice service program employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the organization providing hospice services must maintain professional, financial and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this rule.
  - (a) Nursing services. The hospice service program must provide nursing care and services by or under the supervision of a registered nurse (R.N.) at all times.
    1. Nursing services must be directed and staffed to assure the nursing needs of patients are met.
    2. Patient care responsibilities of nursing personnel must be specified.
    3. Hospice services must be provided in accordance with recognized standards of practice.
    4. A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
      - (i) The deceased was receiving the services of a licensed home care organization providing Medicare-certified hospice services;
      - (ii) Death was anticipated, and the attending physician and/or the hospice medical director has agreed in writing to sign the death certificate. Such agreement must be present with the deceased at the place of death;
      - (iii) The nurse is licensed by the state; and,
      - (iv) The nurse is employed by the home care organization providing hospice services to the deceased.
  - (b) Medical Social Services. Medical Social Services must be provided by a qualified social worker under the direction of a physician.

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

**CHAPTER 1200-8-29  
STANDARDS FOR HOMECARE ORGANIZATIONS  
PROVIDING HOME MEDICAL EQUIPMENT**

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**1200-8-29-.01 DEFINITIONS.**

- (1) 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.
- (2) 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.
- (3) Agency. A Home Care Organization providing home medical equipment.
- (4) 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.
- (5) Assistive Technology Supplier (ATS). Service providers involved in the sale and service of commercially available wheeled mobility devices.
- (6) Board. The Tennessee Board for Licensing Health Care Facilities.
- (7) 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.
- (8) 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.

(Rule 1200-8-29-.01, continued)

- (9) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.
- (10) Competent. For the purpose of this chapter only, a patient who has decision-making capacity.
- (11) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:
  - (a) the action(s) implemented to prevent the reoccurrence of the unusual event,
  - (b) the time frames for the action(s) to be implemented,
  - (c) the person(s) designated to implement and monitor the action(s), and
  - (d) the strategies for the measurements of effectiveness to be established.
- ~~(12) Credentialed Wheeled Mobility Person. A health care professional, licensed under Title 63, whose scope of practice includes the authority to evaluate individuals for prescribed wheeled mobility devices and the authority to recommend them; or 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). (Delete.)~~
- (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.
- (14) Department. The Tennessee Department of Health.
- (15) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.
- (16) Evaluation. The determination and documentation of the physiological and functional factors that impact the selection of an appropriate seating and wheeled mobility device.
- (17) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.
- (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.
- (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

(Rule 1200-8-29-.01, continued)

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 1200-8-29-.13 or T.C.A. §33-3-220.

(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.

(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;

(Rule 1200-8-29-.01, continued)

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.
- (22) Home medical equipment provider. Any person who provides home medical equipment services.
- (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.
- (24) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.
- (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.
- (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).
- (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.
- (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.
- (29) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.
- (30) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (31) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (32) 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;

(Rule 1200-8-29-.01, continued)

- (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) 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) 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.
- (35) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; 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 such living will shall not be deemed "patient abuse" for purposes of these rules.
- (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.
- ( ) Qualified Rehabilitation Professional. A health care professional within 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).
- (37) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (38) Shall or Must. Compliance is mandatory.
- (39) 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.
- (40) 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.
- (41) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(Rule 1200-8-29-.01, continued)

(42) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

~~(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. (Delete.)~~

(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, 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, 68-11-226, 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.

**1200-8-29-.02 LICENSING PROCEDURES.**

(1) No person, partnership, association, corporation or any 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 only for the premises listed in the application for licensure and for the geographic area specified by the certificate of need at the time of the original licensing. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30<sup>th</sup>. The license shall be conspicuously posted in the agency.

(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.

(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

- (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.

**1200-8-29-.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:
  - (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.
- (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;

(Rule 1200-8-29-.06, continued)

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:
- (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 related health care 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.

(Rule 1200-8-29-.06, continued)

- (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 written evaluation and recommendation by a credentialed wheeled mobility person for recipients of prescribed wheeled mobility devices.~~
- (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.
- ~~(e)~~(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.