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Rulemaking Hearing Rule(s) Filing Form

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

Agency/Board/Commission:	Department of Health
Division:	Bureau of Health Licensure and Regulation Division of Health Care Facilities
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Revision Type (check all that apply):
X Amendment
___ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. 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-.01	Definitions
1200-08-01-.07	Optional Hospital Services
1200-08-01-.11	Records and Reports
1200-08-01-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	**Chapter Title**
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1200-08-06-.06	Basic Services
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Chapter Number	**Chapter Title**
1200-08-10	Standards for Ambulatory Surgical Treatment Centers
Rule Number	**Rule Title**
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1200-08-10-.06	Basic Services
1200-08-10-.11	Records and Reports
1200-08-10-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	**Chapter Title**
1200-08-11	Standards for Homes for the Aged
Rule Number	**Rule Title**
1200-08-11-.01	Definitions
1200-08-11-.10	Records and Reports
1200-08-11-.12	Policies and Procedures for Health Care Decision-Making

Chapter Number	**Chapter Title**
1200-08-15	Standards for Residential Hospices
Rule Number	**Rule Title**
1200-08-15-.01	Definitions
1200-08-15-.11	Records and Reports
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Chapter Number	**Chapter Title**
1200-08-24	Standards for Birthing Centers
Rule Number	**Rule Title**
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1200-08-24-.10	Records and Reports
1200-08-24-.12	Policies and Procedures for Health Care Decision-Making

Chapter Number	**Chapter Title**
1200-08-25	Standards for Assisted Care Living Facilities
Rule Number	**Rule Title**
1200-08-25-.02	Definitions
1200-08-25-.13	Reports

Chapter Number	**Chapter Title**
1200-08-26	Standards for Home Care Organizations Providing Home Health Services
Rule Number	**Rule Title**
1200-08-26-.01	Definitions
1200-08-26-.11	Records and Reports
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Chapter Number	**Chapter Title**
1200-08-27	Standards for Home Care Organizations Providing Hospice Services
Rule Number	**Rule Title**
1200-08-27-.01	Definitions
1200-08-27-.11	Records and Reports
1200-08-27-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	**Chapter Title**
1200-08-28	Standards for HIV Supportive Living Centers
Rule Number	**Rule Title**
1200-08-28-.01	Definitions
1200-08-28-.11	Records and Reports
1200-08-28-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	Chapter Title
1200-08-29	Standards for Home Care Organizations Providing Home Medical Equipment
Rule Number	**Rule Title**
1200-08-29-.01	Definitions
1200-08-29-.11	Records and Reports

Chapter Number	Chapter Title
1200-08-32	Standards for End Stage Renal Dialysis Clinics
Rule Number	**Rule Title**
1200-08-32-.01	Definitions
1200-08-32-.11	Records and Reports
1200-08-32-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	Chapter Title
1200-08-34	Standards for Home Care Organizations Providing Professional Support Services
Rule Number	**Rule Title**
1200-08-34-.01	Definitions
1200-08-34-.11	Records and Reports
1200-08-34-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	Chapter Title
1200-08-35	Standards for Outpatient Diagnostic Centers
Rule Number	**Rule Title**
1200-08-35-.01	Definitions
1200-08-35-.11	Records and Reports
1200-08-35-.13	Policies and Procedures for Health Care Decision-Making

Chapter Number	Chapter Title
1200-24-05	Review of Health Care Facility Construction Plans and Specifications
Rule Number	**Rule Title**
1200-24-05-.03	Fees

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Rulemaking Hearing Rules
for the
Board for Licensing Health Care Facilities
Division of Health Care Facilities
Bureau of Health Licensure and Regulation

Chapter 1200-08-01
Standards for Hospitals

Amendments

Rule 1200-08-01-.01 Definitions is amended by deleting paragraphs (18), (91) and (92) and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (89) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(89) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-01-.07 Optional Hospital Services is amended by deleting the subparagraph (1)(d) in its entirety and substituting instead the following language, so that as amended the new subparagraph shall read:

(d) A hospital may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (LPN) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.

Authority: T.C.A. §§ 68-11-209 and 68-57-105.

Rule 1200-08-01-.11 Records and Reports is amended by deleting paragraph (4) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(4) A report of fetal death shall be completed by the hospital for each dead fetus delivered where the fetus weighs three hundred fifty (350) grams or more, or in the absence of weight, is of twenty (20) completed weeks of gestation or more. The report shall be in a form or format approved by the State Registrar and shall be submitted to the department's Office of Vital Records within ten (10) days of the delivery.

Rule 1200-08-01-.11 Records and Reports is amended by deleting paragraph (8) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(8) The hospital shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-01-.11 Records and Reports is amended by adding a new paragraph (9) and renumbering the remaining paragraphs accordingly:

(9) The hospital shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-3-102, 68-11-209 and 68-11-211.

Rule 1200-08-01-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read::

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-01-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-01-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-02
Standards for Prescribed Child Care Centers
Amendments

Rule 1200-08-02-.01 Definitions is amended by deleting paragraph (75) in its entirety and substituting it instead with the following:

(75) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-02-.10 Records and Reports is amended by deleting subparagraph (1)(c) in its entirety. This rule is further amended by adding the following language as new paragraphs (2) and (3):

(2) The PCCC shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The PCCC shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the PCCC or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-02-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-02-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-02-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-06
Standards for Nursing Homes
Amendments

Rule 1200-08-06-.01 Definitions is amended by deleting paragraphs (11), (70) and (71) and renumbering the remaining paragraphs accordingly and further amended by deleting newly renumbered paragraph (68) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(68) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-06-.06 Basic Services is amended by adding a new paragraph (12) so that, as amended, the new paragraph shall read:

(12) Ventilator Services. A nursing home that provides ventilator services shall meet or exceed the following minimum standards by:

(a) Ensuring a licensed respiratory care practitioner as defined by Tennessee Code Annotated Section 63-27-102(7), shall be physically present at the facility twenty four (24) hours per day, seven (7) days per week to provide:

1. ventilator care;

2. administration of medical gases;

3. administration of aerosol medications; and

4. diagnostic testing and monitoring of life support systems;

(b) Ensuring that an appropriate, individualized plan of care is prepared for each patient requiring ventilator services. The plan of care shall be developed with input and participation from a pulmonologist or a physician with experience in ventilator care;

(c) Ensuring that admissions criteria is established to ensure the medical stability of ventilator-dependent patients prior to transfer from an acute care setting;

(d) Ensuring that Arterial Blood Gas (ABG) is readily available in order to document the patient's acid base status and/or End Tidal Carbon Dioxide (etCOs) and whether continuous pulse oximetry measurements should be performed in lieu of ABG studies;

(e) Ensuring that an audible, redundant external alarm system is located outside of each ventilator-dependent patient's room for the purpose of alerting caregivers of patient disconnection, ventilator disconnection or ventilator failure;

(f) Ensuring that the nursing home is equipped with emergency suction equipment and an adequate number of Ambu bags for manual ventilation;

(g) Ensuring that ventilator equipment is connected to electrical outlets connected to back-up generator power;

(h) Ensuring that ventilators are equipped with battery back-up systems;

(i) Ensuring that the nursing home is equipped to employ the use of current ventilator technology consistent with meeting patients' needs for mobility and comfort; and

(j) Ensuring that a back-up ventilator is available at all times.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-06-.11 Records and Reports is amended by deleting paragraph (2) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(2) The nursing home shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-06-.11 Records and Reports is amended by adding a new paragraph (3) and renumbering the remaining paragraphs accordingly:

(3) The nursing home shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the nursing home or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-06-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-06-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-06-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-10
Standards for Ambulatory Surgical Treatment Centers
Amendments

Rule 1200-08-10-.01 Definitions is amended by deleting paragraphs (17), (72) and (73) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting new renumbered paragraph (70) and substituting instead the following language, so that as amended the newly renumbered paragraph shall read:

(70) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-10-.06 Basic Services is amended by deleting subparagraph (1)(f) it its entirety and substituting instead the following language, so that as amended the new subparagraph shall read:

(f) An ASTC may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (L.P.N.) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.

Authority: T.C.A. §§ 68-11-209 and 68-57-105.

Rule 1200-08-10-.11 Records and Reports is amended by deleting paragraph (4) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(4) The ASTC shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-10-.11 Records and Reports is amended by adding a new paragraph (5) and renumbering the remaining paragraphs accordingly:

(5) The ASTC shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ASTC or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-10-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-10-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing

Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-10-.13, Policies and Procedures for Health Care Decision-Making, is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

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

Rule 1200-08-11-.01 Definitions is amended by deleting paragraphs (11), (50) and (51) and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (48) in its entirety and substituting it instead with the following language, so that as amended the newly renumbered paragraph shall read:

(48) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-11-.10 Records and Reports is amended by deleting paragraph (2) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(2) The RHA shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-11-.10 Records and Reports is amended by adding a new paragraph (3) and renumbering the remaining paragraphs accordingly:

(3) The RHA shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the RHA or to the health and safety of its residents and personnel; and

(d) Fires at the RHA that disrupt the provision of resident services or cause harm to the residents or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-11-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-11-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-11-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the

receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-15
Standards for Residential Hospices
Amendments

Rule 1200-08-15-.01 Definitions is amended by deleting paragraphs (15), (83) and (84) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (81) in its entirety and substituting it instead with the following language, so that as amended the newly renumbered paragraph shall read:

(81) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-15-.11 Records and Reports is amended by deleting paragraph (3) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(3) The residential hospice shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-15-.11 Records and Reports is amended by adding a new paragraph (4) and renumbering the remaining paragraphs accordingly:

(4) The residential hospice shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the residential hospice or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-15-.13 Policies and Procedures for Health Care Decision-Making, is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-15-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-15-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-24
Standards for Birthing Centers
Amendments

Rule 1200-08-24-.01 Definitions is amended by deleting paragraphs (12), (52) and (53) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (50) in its entirety and substituting it instead with the following language, so that as amended the newly renumbered paragraph shall read:

(50) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-24-.10 Records and Reports is amended by deleting paragraph (4) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(4) The birthing center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-24-.10 Records and Reports is amended by adding a new paragraph (5) and renumbering the remaining paragraphs accordingly:

(5) The birthing center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the birthing center or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-24-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-24-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-24-.12 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-25
Standards for Assisted Care Living Facilities
Amendments

Rule 1200-08-25-.02 Definitions is amended by deleting paragraph (37).

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-25-.13 Reports is amended by deleting paragraph (1) in its entirety and substituting it instead with the following:

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

Rule 1200-08-25-.13 Reports is amended by adding a new paragraph (2) and renumbering the remaining paragraphs accordingly.

(2) The ACLF shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ACLF or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Chapter 1200-08-26
Standards for Home Care Organizations Providing Home Health Services
Amendments

Rule 1200-08-26-.01 Definitions is amended by deleting paragraphs (14), (66) and (67) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered

paragraph (64) and substituting it instead with the following language, so that as amended, the newly renumbered paragraph shall read:

(64) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-26-.11 Records and Reports is amended by deleting paragraph (2) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(2) The agency providing home health services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-26-.11 Records and Reports is amended by adding a new paragraph (3) and renumbering the remaining paragraphs accordingly:

(3) The agency providing home health services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-26-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-26-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-26-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-27
Standards for Home Care Organizations Providing Hospice Services
Amendments

Rule 1200-08-27-.01 Definitions is amended by deleting paragraphs (15), (71) and (72) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (69) and substituting it instead with the following language, so that as amended, the newly renumbered paragraph shall read:

(69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-27-.11 Records and Reports is amended by deleting paragraph (2) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(2) The agency providing hospice services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-27-.11 Records and Reports is amended by adding a new paragraph (3) and renumbering the remaining paragraphs accordingly:

(3) The agency providing hospice services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-27-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-27-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-27-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the

Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-28
Standards for HIV Supportive Living Centers
Amendments

Rule 1200-08-28-.01 Definitions is amended by deleting paragraphs (15), (80) and (81) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (78) and substituting it instead with the following language, so that as amended, the newly renumbered paragraph shall read:

(78) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-28-.11 Records and Reports is amended by deleting paragraph (3) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(3) The HIV supportive living facility shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-28-.11 Records and Reports is amended by adding a new paragraph (4) and renumbering the remaining paragraphs accordingly:

(4) The HIV supportive living facility shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the HIV supportive living facility or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-28-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-28-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended, the subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-28-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-29
Standards for Home Care Organizations Providing Home Medical Equipment
Amendments

Rule 1200-08-29-.01 Definitions is amended by deleting paragraphs (11), (41) and (42) and renumbering the remaining paragraphs accordingly.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-29-.11 Records and Reports is amended by deleting paragraph (1) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

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

Rule 1200-08-29-.11 Records and Reports is amended by adding a new paragraph (2) and renumbering the remaining paragraphs accordingly:

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

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Chapter 1200-08-32
Standards for End Stage Renal Dialysis Clinics
Amendments

Rule 1200-08-32-.01 Definitions is amended by deleting paragraphs (13), (71) and (72) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (69) and substituting it instead with the following language, so that as amended, the newly renumbered paragraph shall read:

(69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-32-.11 Records and Reports is amended by deleting paragraph (2) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(2) The renal dialysis clinic shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-32-.11 Records and Reports is amended by adding a new paragraph (3) and renumbering the remaining paragraphs accordingly:

(3) The renal dialysis clinic shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ESRD or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-32-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-32-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-32-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-34
Standards for Home Care Organizations Providing Professional Support Services
Amendments

Rule 1200-08-34-.01 Definitions is amended by deleting paragraphs (6), (14), (58) and (59) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (55) and substituting it instead with the following language, so that as amended, the newly renumbered paragraph shall read:

(55) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-34-.11 Records and Reports is amended by deleting paragraph (2) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(2) The agency providing professional support services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-34-.11 Records and Reports is amended by adding a new paragraph (3):

(3) The agency providing professional support services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the home care organization providing professional support services or to the health and safety of its consumers and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-34-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-34-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person

authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-34-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-08-35
Standards for Outpatient Diagnostic Centers
Amendments

Rule 1200-08-35-.01 Definitions is amended by deleting paragraphs (18), (73) and (74) in their entirety and renumbering the remaining paragraphs accordingly and is further amended by deleting newly renumbered paragraph (71) and substituting it instead with the following language, so that as amended, the newly renumbered paragraph shall read:

(71) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 68-11-209, 68-11-211 and 68-11-224.

Rule 1200-08-35-.11 Records and Reports is amended by deleting paragraph (4) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(4) The outpatient diagnostic center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

Rule 1200-08-35-.11 Records and Reports is amended by adding a new paragraph (5) and renumbering the remaining paragraphs accordingly:

(5) The outpatient diagnostic center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the outpatient diagnostic center or to the health and safety of its patients and personnel; and

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

Authority: T.C.A. §§ 68-11-209 and 68-11-211.

Rule 1200-08-35-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting paragraph (5) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

Rule 1200-08-35-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(a) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

Rule 1200-08-35-.13 Policies and Procedures for Health Care Decision-Making is amended by deleting subparagraph (30)(e) in its entirety and substituting it instead with the following language, so that as amended, the new subparagraph shall read:

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

Authority: T.C.A. §§ 68-11-209, 68-11-224 and 68-11-1805.

Chapter 1200-24-05
Review of Health Care Facility Construction Plans and Specifications
Amendments

Rule 1200-24-05-.03 Fees is amended by deleting paragraph (1) in its entirety and substituting it instead with the following language, so that as amended, the new paragraph shall read:

(1) The fee schedule for review of plans and specifications for construction shall be specified in the following table:

Total Project Construction Cost	Fee
$0.00 to $1,000,000.00	$2.50 per thousand or fraction thereof ($250.00 minimum)
$1,000,000.01 or more	$2,500.00 for the first $1,000,000.00 plus $2.00 for each additional thousand or fraction thereof.

Authority: T.C.A §§ 68-11-202, 68-11-209 and 68-11-216.

Rule 1200-24-05-.03 Fees is amended by adding new subparagraphs (2)(a) and (b), and new paragraphs (3), and (4) as follows and renumbering the remaining paragraphs accordingly:

(a) The fee for obtaining a letter stating that plans are not required to be reviewed (a "no review letter") shall be one hundred dollars ($100.00).

(b) The fee shall be applied to the fee for review of plans and specifications for construction if it is determined that plans are required to be reviewed.

(3) The fee for review of plans and specifications for minor renovations, locking hardware, hood and duct suppression shall be three hundred dollars ($300.00).

(4) The fee for review of plans and specifications for Homes for the Aged (RHAs) licensed for six (6) beds or fewer shall be three hundred dollars ($300.00).

Authority: T.C.A §§ 68-11-202, 68-11-209 and 68-11-216.

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)
Dr. Larry Arnold	X				
Sylvia J. Burton	X				
Dr. Thomas M. Carr, Jr.				X	
Paula L. Collier	X				
Betsy Cummins	X				
Alex Gaddy	X				
Robert Gordon, Ph.D.	X				
Dr. Jennifer Gordon-Maloney				X	
C. Luke Gregory				X	
Mike Hann				X	
Janice M. Hill, R.N.	X				
Dr. Roy King				X	
Carissa S. Lynch, Pharm.D.	X				
Annette Marlar	X				
John Marshall	X				
Sara Snodgrass	X				
James V. Weatherington				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 11/10/2010, 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: *09/17/10*

Rulemaking Hearing(s) Conducted on: (add more dates). *11/10/10*

Date: 7/21/11.

Signature: Alison G. Cleaves

Name of Officer: Alison G. Cleaves

Title of Officer: Chief Deputy General Counsel, Department of Health

Subscribed and sworn to before me on: 7/21/11

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 7/7/2011

THEODORA P. WILKINS NOTARY PUBLIC AT LARGE DAVIDSON COUNTY, TENN.

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.
Attorney General and Reporter
8-1-11

Date

Department of State Use Only

Filed with the Department of State on: 01/03/2012

Effective on: 04/02/2012

Tre Hargett

Tre Hargett
Secretary of State

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SECRETARY OF STATE
PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

PUBLIC HEARING COMMENTS

TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

The rulemaking hearing for the Tennessee Department of Health, Board for Licensing Health Care Facilities was held on November 10, 2010 in the Department of Health Conference Center's Iris Room on the First Floor of the Heritage Place Building in MetroCenter, Nashville, Tennessee. Alison G. Cleaves, Deputy General Counsel, presided over the hearing.

Several written comments were submitted prior to the rulemaking hearing, and several comments were made during the meeting.

Dr. Ralph Ruckle submitted written comments with suggestions for amending the POST form to make it easier for patients and health care personnel to understand.

The Board stated they appreciate the comments, but this rulemaking is not to amend the POST form. The Board stated if they decide in the future to amend the POST form, they will take the comments into consideration. The Board took no action on Dr. Ruckle's suggestions at this time since the POST form itself was not part of the current rulemaking.

The Tennessee End of Life Partnership, Inc. (TELP) submitted a written statement, however at the meeting stated they were now in agreement with the rules as proposed and would have withdrawn their written comments if they had been aware they were able to withdraw.

Based on TELP's statement that TELP agreed with the rules contained in the notice of rulemaking and that they would have withdrawn its comments, the chairman stated that these statements required no discussion or comment from the Board.

The Tennessee Health Care Association (THCA) submitted written comments prior to the meeting referencing the UDNR form and the POST form. The THCA feels there is and still may be confusion regarding the use of the POST form, and suggests modifying the language of the proposed rules slightly to clarify that the POST form **may** be used as the UDNR form, but its use is **mandatory** in transfers of individuals from one facility to another. Chris Puri, (Bradley Arant Boult Cummings) spoke representing THCA and agreed the POST form should be mandatory across transfer settings, but its should not be obligatory on any specific facility.

The Board made no comment as to the letter from THCA or Mr. Puri's comments.

A written comment was received from Fresenius Medical Care referencing the proposed change to 1200-08-32-.11 asking for the language to be expanded to further define a "disruption of any service." Further, in the letter it was stated there appeared to be inconsistency in 1200-08-32-.01 and 1200-08-32-.13 in the use of the UNDR and POST form and asked that the Board consider changing the language in these rules. The letter also referenced the term "resident" in 1200-08-32-.13.

The Board commented that the term "vital" in 1200-08-32-.11 takes into consideration that some disruptions may occasionally occur and the language in the rule needs no further defining since this is taken directly from T.C.A. § 68-11-211 and that the rule language needs no clarification. The Board further commented there needs to be no change in 1200-08-32-.01 and 1200-08-32-.13 regarding the use of the POST form. The Board voted to make the suggested change and substitute "individual" for "resident" in 1200-08-32-.13 and in all other rules where this wording occurs.

Regulatory Flexibility Addendum
Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 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 proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.

(2) The proposed rules exhibit clarity, conciseness, and lack of ambiguity.

(3) The proposed rules are not written with special consideration for the flexible compliance and/or reporting requirements because the licensing boards have, as their primary mission, the protection of the health, safety and welfare, of Tennesseans. However, the rules proposed rules are written with a goal of avoiding unduly onerous regulations.

(4) The schedules and deadlines throughout the proposed rules are as "user-friendly" as possible while still allowing the Division to achieve its mandated mission in licensing health care facilities. There is generally sufficient notice between the rulemaking hearing and the final promulgation of rules to allow services and providers to come into compliance with the proposed rules.

(5) Compliance requirements are not consolidated or simplified for small businesses in the proposed rules for the protection of the health, safety and welfare, of Tennesseans.

(6) The standards required in the proposed rules are very basic and do not necessitate the establishment of performance standards for small businesses.

(7) There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

1. **Name of Board, Committee or Council:** Board for Licensing Health Care Facilities.

2. **Rulemaking hearing date:** November 10, 2010.

3. **Types of small businesses that will be directly affected by the proposed rules:**

   Hospitals, Residential Homes for the Aged, Licensed Prescribed Child Care Centers, Nursing Homes, Ambulatory Surgical Treatment Centers, Homes for the Aged, Residential Hospices, Birthing Centers, Assisted Care Living Facilities, Home Care Organizations Providing Home Health Services, Home Care Organizations Providing Hospice Services, HIV Supportive Living Facilities, Home Care Organizations Providing Home Medical Equipment, End Stage Renal Dialysis Clinics, Home Care Organizations Providing Professional Support Services, Outpatient Diagnostic Centers, .

4. **Types of small businesses that will bear the cost of the proposed rules:**

   The proposed rules will not increase costs to small businesses.

5. **Types of small businesses that will directly benefit from the proposed rules:**

   Unknown.

6. **Description of how small business will be adversely impacted by the proposed rules:**

   Small businesses will not be adversely impacted by the proposed rules.

7. **Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:**

   The Board does not believe there are less burdensome alternatives to the proposed rule amendments.

8. **Comparison with Federal and State Counterparts:**

   Unknown.

Impact on Local Governments

Pursuant to T.C.A. 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://state.tn.us/sos/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

It is not expected that these amendments to the rules will have an effect on local governments.

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;

Rules 1200-08-01-.01, 1200-08-02-.01, 1200-08-06-.01, 1200-08-10-.01, 1200-08-11-.01, 1200-08-15-.01, 1200-08-24-.01, 1200-08-26-.01, 1200-08-27-.01, 1200-08-28-.01, 1200-08-32-.01, 1200-08-24-.01, 1200-08-35-.01 amend the definition for a "universal do not resuscitate order" to remove references that 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. The removal of this language allows facilities the option of using the POST form or another form developed by the facility that meets the requirements contained in law.

Rules 1200-08-01-.07 and 1200-08-10-.06 provide a definition for a "scrub nurse" as being a registered nurse or either a licensed practical nurse or surgical technologist supervised by a registered nurse who works directly with a surgeon in the sterile field; current rules for each applicable facility type do not contain this definition.

Rules 1200-08-01-.11 was amended to comport with the law change (Public Chapter 778 of the 2010 Public Acts) that changed the gestational age and weight of stillbirth child.

Rules 1200-08-01-.11, 1200-08-02-.10, 1200-08-06-.11, 1200-08-10-.11, 1200-08-11-.10, 1200-08-15-.11, 1200-08-24-.10, 1200-08-26-.11, 1200-80-27-.11, 1200-08-28-.11, 1200-08-29-.11, 1200-08-32-.11, 1200-08-34-.11, 1200-08-35-.11 amend current rules to remove references to the unusual incident reporting system because applicable law (T.C.A. §68-11-224) was amended to remove the terms "unusual event" or "unusual incident" and to change the reporting requirements for facilities so that facilities are no longer required to report all unusual events contained in statute and are required to report incidents of abuse, neglect and misappropriation.

Rules 1200-08-01-.13, 1200-08-02-.12, 1200-08-06-.13, 1200-08-10-.13, 1200-08-11-.12, 1200-08-15-.13, 1200-08-24-.12, 1200-08-26-.13, 1200-08-27-.13, 1200-08-28-.13, 1200-08-32-.13, 1200-08-34-.13, 1200-08-35-.13 were amended to provide that that the Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities is only the mandatory DNR form in transfer situations where the resident/patient is being transferred from one facility to another. In all other situations, the Board is no longer mandating that the facility must use the POST form; the facility has the option of using the POST form or another form developed by the facility that meets the requirements contained in law.

Rule 1200-08-06-.06 provides the minimum standards for ventilator services in nursing home; current rules do not contain these standards.

Rule 1200-08-24-05-.02 amends the current rules to increase the plans review fees in reviewing plans and specifications for the construction of health care facilities.

(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;

The following are the state laws that provide authority for the promulgation of these rules: T.C.A. §§68-11-209 and 6811-216, which contain the Board's general rulemaking authority; T.C.A. §68-11-211, which was revised in 2009 to require only the reporting of abuse, neglect and misappropriation; T.C.A. §68-11-224, which provides that the Board shall promulgate rules and create forms for the withholding of resuscitative services; T.C.A. §68-11-1805, which provides that the Board shall develop and issue appropriate model forms for advanced directives.

(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;

All licensees licensed by the Board for Licensing Health Care Facilities are affected by these rules, i.e., hospitals, prescribed child care centers, nursing homes, ambulatory surgical treatment centers, resident homes for the aged, residential hospices, birthing centers, assisted care living facilities, home care organizations, HIV supportive living facilities, end stage renal dialysis clinics, and outpatient diagnostic centers.

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

Attorney General's Opinion, Opinion No.: 05-093, June 13, 2005 is related to these rules. I do not know of any judicial ruling that directly relates to these rules.

(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;

The rules will have neither a positive nor a negative fiscal impact, but will maintain the self-sufficiency of the program.

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

Alison Cleaves, Chief Deputy General Counsel, Department of Health Office of General Counsel, Plaza One, Suite 210, 220 Athens Way, Nashville, Tennessee 37243, (615) 741-1611 and Vincent Davis, Director, Division of Health Care Facilities, Heritage Place, 227 French Landing, Suite 500, Nashville, Tennessee 37243, (615) 741-7532.

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

Alison Cleaves, Chief Deputy General Counsel, Department of Health Office of General Counsel, Plaza One, Suite 210, 220 Athens Way, Nashville, Tennessee 37243 and Vincent Davis, Director, Heritage Place, 227 French Landing, Suite 500, Nashville, Tennessee 37243

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

Alison Cleaves, Chief Deputy General Counsel, Department of Health Office of General Counsel, Plaza One, Suite 210, 220 Athens Way, Nashville, Tennessee 37243, (615) 741-1611, Alison.Cleaves@tn.gov and Vincent Davis, Director, Heritage Place, 227 French Landing, Suite 500, Nashville, Tennessee 37243, (615) 741-7532, Vincent.Davis@tn.gov

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

I or Vincent Davis will provide any additional information requested by the Committee.

REDLINE

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

CHAPTER 1200-08-01
STANDARDS FOR HOSPITALS

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1200-08-01-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division shall approve a hospital's acceptable plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

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

(6) 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.

(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 ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents

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

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) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

(9) Certified Nurse Practitioner. A person who is licensed as a registered nurse and has further been issued a certificate of fitness to prescribe and/or issue legend drugs by the Tennessee Board of Nursing.

(10) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(11) Certified Respiratory Therapist. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

(12) Certified Respiratory Therapy Technician. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

(13) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

(14) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professional, e.g., licensed physicians and mid-level practitioners.

(15) Collaborative Plan. The formal written plan between the mid-level practitioners and a licensed physician.

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

(17) Competent. A patient who has capacity.

(18) 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.

~~(19) Critical Access Hospital. A hospital located in a rural area, certified by the Department as being a necessary provider of health care services to residents of the area, which makes available twenty-four (24) hour emergency care; is a designated provider in a rural health network; provides not more than twenty-five (25) acute care inpatient beds for providing inpatient care not to exceed an annual average of ninety-six (96) hours, and has a quality assessment and performance improvement program and procedures for utilization review. If swing-bed approval has been granted, all twenty-five (25) beds can be used interchangeably for acute or Skilled Nursing Facility (SNF/swing-bed) level of care services.~~

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

(~~20~~19) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(~~21~~20) Department. The Tennessee Department of Health.

(~~22~~21) 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.

(~~23~~22) Designation. An official finding and recognition by the Department of Health that an acute care hospital meets Tennessee State Rural Health Care Plan requirements to be a Critical Access Hospital.

(~~24~~23) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners. Persons exempt from licensure shall be registered with the American Dietetics Association pursuant to T.C.A. §63-25-104.

(~~25~~24) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical records 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.

(~~26~~25) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(~~27~~26) 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.

(~~28~~27) 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.

(~~29~~28) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(~~30~~29) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~31~~30) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

(~~32~~31) 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).

(~~33~~32) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~34~~33) 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

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

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 1200-08-01-.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.

(~~35~~34) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~36~~35) 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.

(~~37~~36) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment. All hospitals shall provide basic hospital functions and may provide optional services as delineated in these rules. A hospital shall be designated according to its classification and shall confine its services to those classifications described below.

(a) General Hospital. To be licensed as a general hospital, the institution shall maintain and operate organized facilities and services to accommodate one or more non-related persons for a period exceeding twenty-four (24) hours for the diagnosis, treatment or care of such persons and shall provide medical and surgical care of acute illness, injury or infirmity and obstetrical care. All diagnosis, treatment and care shall be administered by or performed under the direction of persons currently licensed to practice the healing arts in the State of Tennessee. In addition, a general hospital must specifically provide:

1. An organized staff of professional, technical and administrative personnel.

2. A laboratory with sufficient equipment and personnel necessary to perform biochemical, bacteriological, serological and parasitological tests.

3. X-ray facilities which shall include, as a minimum requirement, a complete diagnostic radiographic unit.

4. A separate surgical unit which shall include, as minimum requirements, one operating room, a sterilizing room, a scrub-up area and workroom.

5. Obstetrical facilities which shall include, as minimum requirements, one delivery room, a labor room, a newborn nursery, an isolation nursery, and patient rooms designated exclusively for obstetrical patients.

6. An emergency department in accordance with rule 1200-08-01-.07(5) of these standards and regulations.

(b) Satellite Hospital. A satellite hospital may be licensed with a parent hospital upon approval by the Board for Licensing Health Care Facilities when they are on separate premises and are operated under the same management.

(c) Chronic Disease Hospital. To be licensed as a chronic disease hospital, the institution shall be devoted exclusively to the diagnosis, treatment or care of persons needing medical, surgical or rehabilitative care for chronic or long-term illness, injury, or infirmity. The diagnosis, treatment or care shall be administered by or performed under the direction of persons currently licensed to practice the healing arts in the State of Tennessee. A chronic disease hospital shall meet the requirements for a general

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

hospital except that obstetrical facilities are not required and, if the hospital provides no surgical services, an emergency department is not required.

(d) Orthopedic Hospital. To be licensed as an orthopedic hospital, the institution shall be devoted primarily to the diagnosis and treatment of orthopedic conditions. An orthopedic hospital shall meet the requirements for a general hospital except that obstetrical services are not required and, if the hospital provides no surgical services, an emergency department is not required.

(e) Pediatric Hospital. To be licensed as a pediatric hospital, the institution shall be devoted primarily to the diagnosis and treatment of pediatric cases and have on staff professional personnel especially qualified in the diagnosis and treatment of the diseases of children. A pediatric hospital shall meet the requirements of a general hospital except that obstetrical facilities are not required and if the hospital provides no surgical services, an emergency department is not required.

(f) Eye, Ear, Nose, and Throat Hospital or any one of these. To be licensed as an eye, ear, nose and throat hospital, the institution shall be devoted primarily to the diagnosis and treatment of the diseases of the eye, ear, nose, and throat. The hospital shall have on staff professional personnel especially qualified in the diagnosis and treatment of diseases of the eye, ear, nose and throat. An eye, ear, nose and throat hospital shall meet the requirements for a general hospital except that obstetrical facilities are not required and, if the hospital provides no surgical services, an emergency department is not required.

(g) Rehabilitation Hospital. To be licensed as a rehabilitation hospital, the institution shall be devoted primarily to the diagnosis and treatment of persons requiring rehabilitative services. A rehabilitation hospital shall meet the requirement of a general hospital except that radiology services, a surgical unit, obstetrical facilities, and an emergency department are not required.

(~~38~~37) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such persons, and maternity care involving labor and delivery for any period of time.

(~~39~~38) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~40~~39) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~41~~40) 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.

(~~42~~41) Involuntary Transfer. The movement of a patient between hospitals, without the consent of the patient, the patient's legal guardian, next of kin or representative.

(~~43~~42) Justified Emergency. Includes, but is not limited to, the following events/ occurrences:

(a) An influx of mass casualties;

(b) Localized and/or regional catastrophes such as storms, earthquakes, tornadoes, etc. or,

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

(c) Epidemics or episodes of mass illness such as influenza, salmonella, etc.

(~~44~~43) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~45~~44) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~46~~45) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~47~~46) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~48~~47) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part, which includes labor when delivery is imminent, when there is inadequate time to effect safe transfer to another hospital prior to delivery, or when a transfer may pose a threat to the health and safety of the patient or the unborn child.

(~~49~~48) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations. and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~50~~49) Medical Staff. An organized body composed of individuals appointed by the hospital governing board that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(~~51~~50) 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.

(~~52~~51) Member of the Professional Medical Community. A professional employed by the hospital and on the premises at the time of a voluntary delivery.

(~~53~~52) Mid-Level Practitioner. Either a certified nurse practitioner or a physician assistant.

(~~54~~53) N.F.P.A. The National Fire Protection Association.

(~~55~~54) Nuclear Medicine Technologist. A person currently registered as such by the National Association for Nuclear Medicine Technology.

(~~56~~55) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(~~57~~56) Occupational Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

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

(~~58~~57) Occupational Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~59~~58) Optometrist. A person currently licensed as such by the Tennessee Board of Optometry.

(~~60~~59) 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.

(~~61~~60) 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.

(~~62~~61) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~63~~62) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~64~~63) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(~~65~~64) Physical Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~66~~65) Physical Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~67~~66) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~68~~67) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).

(~~69~~68) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(~~70~~69) 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.

(~~71~~70) Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(~~72~~71) 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.

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

(~~73~~72) Radiological Technologist. A person currently registered as such by the American Society of Radiological Technologists.

(~~74~~73) 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.

(~~75~~74) Registered Health Information Administrator (RHIA). A person currently registered as such by the American Health Information Management Association.

(~~76~~75) Registered Health Information Technician (RHIT). A person currently accredited as such by the American Health Information Management Association.

(~~77~~76) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~78~~77) Satellite Hospital. A freestanding hospital licensed with a parent hospital that is on separate premises and operated under the same management.

(~~79~~78) Shall or Must. Compliance is mandatory.

(~~80~~79) Social Worker. A person who has at least a bachelor's degree in Social Work or related field, and preferably, two (2) years medical social work or other community based work experience.

(~~81~~80) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified medical personnel when a physician is not readily available.

(~~82~~81) 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.

(~~83~~82) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board.

(~~84~~83) 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.

(~~85~~84) Surgical Technologist. A person who works under supervision to facilitate the safe and effective conduct of invasive surgical procedures. This individual is usually employed by a hospital, medical office, or surgical center and supervised during the surgical procedure according to institutional policy and procedure to assist in providing a safe operating room environment that maximizes patient safety by performing certain tasks including, but not limited to:

(a) Preparation of the operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments, and equipment using sterile technique;

(b) Preparation of the operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely; and

(c) Passing instruments, equipment or supplies to a surgeon, sponging or suctioning an operative site, preparing and cutting suture material, holding retractors, transferring but

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

not administering fluids or drugs, assisting in counting sponges, needles, supplies, and instruments, and performing other similar tasks as directed during a surgical procedure.

(~~86~~85) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~87~~86) Transfer. The movement of a patient between hospitals at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice. The term does not apply to the commitment and movement of mentally ill and mentally retarded persons and does not apply to the discharge or release of a patient no longer in medical need of hospital care or to a hospital's refusal, after an appropriate medical screening, to render any medical care on the grounds that the person does not have a medical need for hospital care.

(~~88~~87) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(~~89~~88) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such person may be deemed to be the "treating physician."

~~(90) 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.~~

(89) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers

~~(91) 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.~~

~~(92) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~93~~90) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a hospital with any hospital employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, 68-57-102 and 68-57-105.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed November 30, 1984; effective December 30, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 26, 1996; effective July 8, 1996. Amendment filed November 30, 1999; effective February 6, 2000. Repeal, except for Paragraphs (1), (5), (8), (10), (11), (13), (16), (29) and (37) as promulgated February 6, 2000, and new 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. Amendment filed April 11, 2003; effective June 25,*

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

2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed August 27, 2004; effective November 10, 2004. Amendments filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendments filed March 18, 2010; effective June 16, 2010.

(Rule 1200-08-01-.06, continued)

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.

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. Amendment filed December 23, 2009; effective March 23, 2010. Amendment filed March 18, 2010; effective June 16, 2010.*

1200-08-01-.07 OPTIONAL HOSPITAL SERVICES.

(Rule 1200-08-01-.07, continued)

(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.~~

(d) A hospital may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (LPN) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.

(e) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable state laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(f) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(g) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(h) Surgical technologists must:

1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or

2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

3. Have completed an appropriate training program for surgical technologists in the armed forces or at a CAAHEP accredited hospital or CAAHEP accredited ambulatory surgical treatment center; or

4. Successfully complete the surgical technologists LCC-ST certifying exam; or

5. Provide sufficient evidence that, prior to May 21, 2007, the person was at any time employed as a surgical technologist for not less than eighteen (18) months in the three (3) years preceding May 21, 2007 in a hospital, medical office, surgery center, or an accredited school of surgical technology; or has begun the

(Rule 1200-08-01-.07, continued)

appropriate training to be a surgical technologist prior to May 21, 2007, provided that such training is completed within three (3) years of May 21, 2007.

(i) A hospital can petition the director of health care facilities of the department for a waiver from the provisions of 1200-08-01-.07(1)(h) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.

(j) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal.

(k) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(l) Properly executed informed consent, advance directive, and organ donation forms, when applicable, must be in the patient's chart before surgery, except in emergencies.

(m) The following equipment must be available to the operating room suites:

1. Call-in system;

2. Cardiac monitor;

3. Resuscitator;

4. Defibrillator;

5. Aspirator; and

6. Tracheotomy set.

(n) There must be adequate provisions for immediate pre and post-operative care.

(o) The operating room register must be complete and up-to-date.

(p) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

(2) Anesthesia Services.

(a) If the hospital furnishes anesthesia services, they must be provided in a well organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(b) The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by:

(Rule 1200-08-01-.07, continued)

1. A qualified anesthesiologist;

2. A doctor of medicine or osteopathy (other than an anesthesiologist);

3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

4. A certified registered nurse anesthetist (CRNA); or

5. A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(c) Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

1. A pre-anesthesia evaluation or evaluation update conducted within forty-eight (48) hours prior to surgery by an individual qualified to administer anesthesia;

2. An intraoperative anesthesia record;

3. For each inpatient, a written post-anesthesia follow-up report prepared within forty-eight (48) hours following surgery by an individual qualified to administer anesthesia or by the person who administered the anesthesia and submits the report by telephone; and

4. For each outpatient, a post-anesthesia evaluation of anesthesia recovery prepared in accordance with policies and procedures approved by the medical staff.

(3) Nuclear Medicine Services.

(a) If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(b) The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(c) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(d) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(e) Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(f) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(g) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirements for laboratory services as specified in TCA § 68-29-101, et seq.

(Rule 1200-08-01-.07, continued)

(h) Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be:

1. Maintained in safe operating condition; and,

2. Inspected, tested, and calibrated at least annually by qualified personnel.

(i) The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures. Copies of nuclear medicine reports must be maintained for at least ten (10) years.

(j) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(k) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(l) Nuclear medicine services must be ordered only by a practitioner whose scope of federal or state licensure and whose defined staff privileges allow such referrals.

(m) Patients are not left unattended in pre and post procedure areas.

(4) Outpatient Services.

(a) If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(b) Outpatient services must be appropriately organized and integrated with inpatient services.

(c) The hospital must have appropriate professional and non-professional personnel available to provide outpatient services.

(d) Patient's rights, including a phone number to call regarding questions or concerns, shall be made readily available to outpatients.

(e) Outpatient laboratory testing in Tennessee hospitals may be ordered by the following:

1. Any licensed Tennessee practitioner who is authorized to do so by T.C.A. § 68-29-121;

2. Any out of state practitioner who has a Tennessee telemedicine license issued pursuant to rule 0880-02-.16; or

3. Any duly licensed out of state health care professional as listed in T.C.A. § 68-29-121 who is authorized by his or her state board to order outpatient laboratory testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-02-.14(7)(a)1., 2., and 3.

(f) Outpatient diagnostic testing in Tennessee hospitals may be ordered by the following:

1. Any Tennessee practitioner licensed under Title 63 who is authorized to do so by his or her practice act;

(Rule 1200-08-01-.07, continued)

2. Any out of state practitioner who has a Tennessee telemedicine license issued pursuant to rule 0880-02-.16; or

3. Any duly licensed out of state health care professional who is authorized by his or her state board to order outpatient diagnostic testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-02-.14(7)(a)1., 2., and 3.

(5) Emergency Services.

(a) Hospitals that elect to provide surgical services, other than in a separately licensed Ambulatory Surgical Treatment Center, must maintain and operate an emergency room.

(b) If emergency services are provided, the hospital must meet the emergency needs of patients in accordance with acceptable standards of practice. Each hospital must have a policy which assures that all patients who present to the emergency department, are screened/triaged to determine if a medical emergency exists and stabilized when a medical emergency does exist. A hospital may deny access to patients when it is on diversionary status only because it does not have the staff or facilities in the emergency department to accept any additional emergency patients at that time. If an ambulance disregards the hospital's instructions and brings an individual on to the hospital grounds, the individual has arrived on hospital property and cannot be denied access to hospital services. Hospital property, for the purpose of this subparagraph, is considered to be:

1. The hospital's physical geographic boundaries; or

2. Ambulances owned and operated by the hospital, whenever in operation, whether or not on hospital grounds.

(c) A hospital may not delay provision of an appropriate medical screening examination in order to inquire about the individual's method of payment or insurance status.

(d) If emergency services are provided at the hospital:

1. The services must be organized under the direction of a qualified member of the medical staff;

2. The services must be integrated with other departments of the hospital; and

3. The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff. These policies and procedures must define how the hospital will assess, stabilize, treat and/or transfer patients.

(e) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(f) There shall be a sufficient number of emergency rooms and adequate equipment and supplies to accommodate the caseload of the emergency services.

(g) The entrance to the emergency department shall be clearly marked.

(h) Legend drugs in emergency rooms shall be stored in locked cabinets, except as otherwise provided for emergency drugs by the written policies and procedures of the

(Rule 1200-08-01-.07, continued)

hospital. Discharge medications may be dispensed to out-patients upon written physician orders provided that they have been packaged in containers by the pharmacist in amounts not to exceed twelve (12) hours dosage and labeled in accordance with Pharmacy Board rules.

(i) Emergency Room medical records shall include the following:

1. Identification data;

2. Information concerning the time of arrival, means and by whom transported;

3. Pertinent history of the injury or illness to include chief complaint and onset of injuries or illness;

4. Significant physical findings;

5. Description of laboratory, x-ray and EKG findings;

6. Treatment rendered;

7. Condition of the patient on discharge or transfer;

8. Diagnosis on discharge;

9. Instructions given to the patient or his family; and

10. A control register listing chronologically the patient visits to the emergency room. The record shall contain at least the patient's name, date and time of arrival and record number. The name of those dead on arrival shall be entered in the register.

(j) Emergency patients and their families are made aware of their rights, including a number to call regarding concerns or questions.

(6) Rehabilitation Services.

(a) If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients. These disciplines should document their contribution to the plan for patient care.

(b) The organization of the service must be appropriate to the scope of the services offered.

(c) The director of the service must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(d) Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by hospital policy, consistent with state law.

(e) Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services and the orders must be incorporated in the patient's record.

(Rule 1200-08-01-.07, continued)

(7) Obstetrical Services.

(a) If a hospital provides obstetrical services it shall have space, facilities, equipment and qualified personnel to assure appropriate treatment of all maternity patients and newborns.

(b) The hospital must have written policies and procedures governing medical care provided in the obstetrical service which are established by and are a continuing responsibility of the medical staff.

(c) Provisions must be made for care of the patient during labor and delivery, either in the patient's room or in a designated room.

(d) Designated delivery rooms shall be segregated from patient areas and be located so as not to be used as a passageway between or subject to contamination from other parts of the hospital.

(e) A delivery record shall be kept that must indicate:

1. The name of the patient;

2. Her maiden name;

3. Date of delivery;

4. Sex of infant;

5. Name of physician;

6. Names of persons assisting;

7. What complications, if any, occurred;

8. Type of anesthesia used;

9. Name of person administering anesthesia; and

10. Other persons present.

(8) Pediatric Services.

(a) If the hospital provides pediatric services, it shall provide appropriate pediatric equipment and supplies.

(b) Pediatric services must be appropriate to the scope and complexity of the services offered and must meet the needs of the patients in accordance with acceptable standards of practice.

(c) The hospital must have appropriate professional and non-professional personnel available to provide pediatric services.

(9) Respiratory Care Services.

(a) If the hospital provides respiratory care services, the hospital must meet the needs of the patients in accordance with acceptable standards of practice.

(Rule 1200-08-01-.07, continued)

(b) The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(c) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly.

(d) There must be adequate numbers of certified respiratory therapists, certified respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with state law.

(e) Services must be delivered in accordance with medical staff directives.

(f) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(g) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for clinical laboratory services specified in the Tennessee Medical Laboratory Act.

(10) Social Work Services.

(a) If the hospital provides social work services, the services must be available to the patient, the patient's family and other persons significant to the patient, in order to facilitate adjustment of these individuals to the impact of illness and to promote maximum benefits from the health care services provided.

(b) Social work services shall include psychosocial assessment, counseling, coordination of discharge planning, community liaison services, financial assistance and consultation.

(c) Social work services shall be provided by personnel who satisfy applicable accreditation standards and who are in compliance with Tennessee State Law governing social work practices. Social work personnel employed by the hospital prior to the effective date of these regulations shall be deemed to meet this requirement.

(d) Facilities for social work services shall be readily accessible and shall permit privacy for interviews and counseling.

(11) Psychiatric Services.

(a) If a hospital provides psychiatric services, a psychiatric unit devoted exclusively for the care and treatment of psychiatric patients and professional personnel qualified in the diagnosis and treatment of patients with psychiatric illnesses shall be provided. Adequate protection shall be provided for patients and the staff against any physical injury resulting from a patient becoming violent. A psychiatric unit shall meet the requirements as needed to care for patients admitted, either through direct care or by contractual arrangements.

(b) A hospital licensed by the Department of Health as a satellite hospital whose primary purpose is the provision of mental health or mental retardation services, must verify to the Department that Standards of the Department of Mental Health and Mental Retardation are satisfied.

(12) Alcohol and Drug Services.

(Rule 1200-08-01-.07, continued)

(a) If a hospital provides alcohol and drug services, the service shall be devoted exclusively to the care and treatment of alcohol and drug dependent patients and have on staff physicians and other professional personnel qualified in the diagnosis and treatment of alcoholism and drug addiction.

(b) Adequate protection shall be provided for the patients and staff against any physical injury resulting from a patient becoming disturbed or violent. Alcohol and drug services shall meet the requirements as needed to care for patients admitted, either through direct care or by contractual arrangements.

(13) Perinatal and/or Neonatal Care Services. Any hospital providing perinatal and/or neonatal care services shall comply with the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities developed by the Tennessee Department of Health's Perinatal Advisory Committee, June 1997 including amendments as necessary.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-57-101, 68-57-102, ~~and~~ 68-57-104 and 105.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed June 12, 2003; effective August 26, 2003. Amendment filed July 27, 2005; effective October 10, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-01-.08 BUILDING STANDARDS.

(1) The hospital must be constructed, arranged, and maintained to ensure the safety of the patient.

(2) The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(3) No new hospital shall hereafter be constructed, nor shall major alterations be made to existing hospitals, or change in hospital type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new hospital is licensed or before any alteration or expansion of a licensed hospital can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.

(4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities, and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

(5) The codes in effect at the time of submittal of plans and specifications, as defined by these regulations shall be the codes to be used throughout the project.

(Rule 1200-08-01-.10, continued)

(b) The 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 subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious waste shall be stored, transported, 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, 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.*

1200-08-01-.11 RECORDS AND REPORTS.

(1) A report listing all births, deaths and reportable fetal deaths which have occurred in the hospital shall be filed with the local registrar in the county where the institution is located or as otherwise directed by the State Registrar. The report shall be filed on the third (3rd) day of the month after the month in which the event occurred on a form or in a format prescribed by the State Registrar. If no birth, death or reportable fetal death occurred in the hospital, the report should be filed to indicate that fact.

(2) A Certificate of Live Birth shall be prepared for each live birth which occurred in the hospital or en route thereto on a form or in a format prescribed by the State Registrar and submitted to the State Registrar within ten (10) days of the birth.

(3) Immediately before or after the birth of a child to an unmarried woman in the facility, an authorized representative of the facility shall provide the mother, and if present, the biological father:

(a) Written information concerning the benefits, rights and responsibilities of establishing paternity for the child, as provided to the hospital by the Tennessee Department of Human Services;

(b) An Acknowledgment of Paternity Form provided by the department; and

(Rule 1200-08-01-.11, continued)

(c) The opportunity to complete and submit to the hospital the Acknowledgment Form. The original, signed Acknowledgment of Paternity Form shall be submitted with the original birth certificate as directed by the State Registrar. A duplicate original Acknowledgment of Paternity Form shall be filed with the juvenile court of the county where the mother resides. Copies of the acknowledgment form shall be provided to the mother and the father of the child.

~~(4) A report of fetal death shall be completed by the hospital for each dead fetus delivered where the fetus weighs five hundred (500) grams or more, or in the absence of weight, is of twenty-two (22) completed weeks of gestation or more. The report shall be in a form or format approved by the State Registrar and shall be submitted to the department's Office of Vital Records within ten (10) days of the delivery.~~

(4) A report of fetal death shall be completed by the hospital for each dead fetus delivered where the fetus weighs three hundred fifty (350) grams or more, or in the absence of weight, is of twenty (20) completed weeks of gestation or more. The report shall be in a form or format approved by the State Registrar and shall be submitted to the department's Office of Vital Records within ten (10) days of the delivery.

(5) Hospitals shall submit their Joint Annual Report data within one hundred and fifty (150) days after the end of each hospital's fiscal year and within one hundred and five (105) days after closure or a change in ownership. Hospitals shall also submit to the department, at the same time the hospital sends the signed paper copy of the report, a notarized statement from the hospital's chief financial officer stating that the financial data reported on the Joint Annual Report is consistent with the audited financials for the hospital for that reporting year. The notarized statement shall also be attested to by the chief executive officer of the submitting hospital.

(6) Hospitals that fail to file their joint annual report timely or that file a joint annual report that does not include all of the required data elements or includes data that does not pass the department's edits shall receive a deficiency from the department. Within ten (10) calendar days, the hospital shall be required to return a plan of correction indicating: how the deficiency will be corrected; the date upon which each deficiency will be corrected; what measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and how the corrective action will be monitored to ensure the deficient practice does not recur. 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.

(7) The hospital shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Repeated failure to report communicable diseases shall be cause for a revocation of a hospital license.

~~(8) 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;~~

(Rule 1200-08-01-.11, continued)

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;~~

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;~~

(Rule 1200-08-01-.11, continued)

~~(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:~~

~~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~~

(Rule 1200-08-01-.11, continued)

~~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.~~

~~(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.~~

(8) The hospital shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(9) The hospital shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(Rule 1200-08-01-.11, continued)

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel; and

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

(~~9~~10) The hospital shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(~~10~~11) The hospital shall report, at least quarterly to the department, claims data on the UB-92 form or its successor for all discharges from the facility.

(~~11~~12) The hospital shall report to the department information regarding treatment of traumatic brain injuries. The report must be submitted on a form provided by the department and must include the following information:

(a) Name, age, and residence of the injured person; and

(b) Other information as requested by the department which is currently available and collected by computer in the medical records department of the treating hospital.

(~~12~~13) The hospital shall retain legible copies of the following records and reports in the facility in a single file for thirty-six (36) months following their issuance and shall be made available for inspection during normal business hours to any patient who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(f) Federal Health Care Financing Administration surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and finding, if any; and

(i) 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, 68-11-213, and 68-11-310.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed May*

(Rule 1200-08-01-.11, continued)
24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007.

1200-08-01-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

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

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

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

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The hospital must have policies to govern access and duplication of the patient's record;

(f) To have access to a phone number to call if there are questions or complaints about care;

(g) To have appropriate assessment and management of pain; and

(h) To be involved in the decision making of all aspects of their care.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendments filed September 6, 2005; effective November 20, 2005.*

1200-08-01-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each hospital shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include

(Rule 1200-08-01-.13, continued)

individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(Rule 1200-08-01-.13, continued)

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-01-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

(Rule 1200-08-01-.13, continued)

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-01-.13(16)(c) thru 1200-08-01-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-01-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

(Rule 1200-08-01-.13, continued)

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-01-.13(20) thru 1200-08-01-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(Rule 1200-08-01-.13, continued)

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-01-.13(20) thru 1200-08-01-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

(Rule 1200-08-01-.13, continued)

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(Rule 1200-08-01-.13, continued)

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-01-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) All hospitals must have one or more on-site electrical generators which are capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. (It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source).

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, natural gas, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In

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

CHAPTER 1200-08-02
STANDARDS FOR PRESCRIBED CHILD CARE CENTERS

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1200-08-02-.01 DEFINITIONS.

(1) Administrator. The individual designated by the licensee or the governing body to be the person responsible for the day to day supervision and operation of the PCCC and may be either the licensee or the nursing director.

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

(6) 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.

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

(8) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

(9) Certified Nurse Practitioner. A person who is licensed as a registered nurse and has further been issued a certificate of fitness to prescribe and/or issue drugs by the Tennessee Board of Nursing.

(Rule 1200-08-02-.01, continued)

(10) Certified Respiratory Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(11) Child or Children. A person or persons under 18 years of age.

(12) Child Care. The provision of supervision, protection, and meeting, at a minimum, the basic needs of a child for three (3) or more hours a day, but less than twenty-four (24) hours a day.

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

(14) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(15) Department. The Tennessee Department of Health.

(16) 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.

(17) Developmentally Appropriate. As defined by the National Association for the Education of Young Children, developmentally appropriate practice is the use of child development knowledge to identify the range of appropriate behaviors, activities and materials for a specific age group. This knowledge is used in conjunction with understanding about an individual child's growth patterns, strengths, interests, and experiences to design the most appropriate learning environment. Developmentally appropriate curriculum provides for all areas of a child's development: physical, emotional, social, and cognitive through an integrated approach.

(18) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners.

(19) Do Not Resuscitate (DNR) Order. For purposes of this chapter, an order entered by the child's treating physician, in consultation with the parent, in the child's medical record which states that in the event the child 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.

(20) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(21) 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.

(22) Emergency. Any situation or condition which presents an imminent danger of death or serious physical or mental harm to children.

(23) 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 1200-08-02-.01, continued)

(24) Functional Assessment. An evaluation of the child's abilities and needs related to self care, communication skills, social skills, motor skills, pre-academic areas, play with toys/objects, growth and development appropriate for age.

(25) Group. A specific number of children comprising an age range, assigned to specific staff in an assigned space, which is divided from the space of other groups by a recognizable barrier to define limits and to reduce distractions.

(26) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

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

(28) 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).

(29) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(30) Health Care Decision-maker. In the case of an individual who lacks capacity, the individual's health care decision-maker is one of the following: the individual's health care agent as specified in an advance directive, the individual's court-appointed guardian or conservator with health care decision-making authority, the individual's surrogate as determined pursuant to Rule 1200-08-02-.12 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.

(31) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(32) 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 of practice of a profession.

(33) High School Diploma. As used in the context of staff qualifications, refers to a document recognizing graduation from a legally approved institution, public or private, based on the issuing state's required number of academic credits, including passing a GED test. As used in this Chapter, a certificate or statement of attendance or similar document, or correspondence or video courses, do not qualify as a high school diploma.

(34) Holding Out to the Public. Advertising or soliciting the public through the use of personal, telephone, mail or other forms of communication to provide information about services provided by the facility.

(35) Individual instruction. An individual's direction concerning a health care decision for the individual.

(36) Infant. A child who is six (6) weeks through fifteen (15) months of age.

(37) 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.

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

(Rule 1200-08-02-.01, continued)

(39) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

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

(41) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the child's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part, which includes labor when delivery is imminent, when there is inadequate time to effect safe transfer to a hospital prior to delivery, or when a transfer may pose a threat to the health and safety of the child or the unborn child.

(42) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations, and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(43) 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.

(44) Mid-Level Practitioner. A certified nurse practitioner or a licensed physician assistant.

(45) N.F.P.A. The National Fire Protection Association.

(46) Nursing Director. A licensed registered nurse providing continuous supervision of PCCC services and managing the operations of the facility.

(47) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(48) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(49) Optometrist. A person currently licensed as such by the Tennessee Board of Optometry.

(50) Parent. A biological, legal or adoptive parent, guardian, or a legal or physical custodian who has primary responsibility for a child.

(51) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(52) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(53) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(54) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(Rule 1200-08-02-.01, continued)

(55) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(56) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(57) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).

(58) Plan of Care. The comprehensive plan for implementation of medical, nursing, psychosocial, developmental, and educational therapies to be provided upon admission and shall include necessary equipment to meet the child's need, and the plan will be revised to include recommended changes in the therapeutic plans. The disposition to be followed in the event of emergency situations will be specified in the Plan of Care.

(59) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(60) 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.

(61) Prescribed Child Care Center (PCCC). A nonresidential child care, health care/child care center providing physician prescribed services and appropriate developmental services for six (6) or more children who are medically and/or technology dependent and require continuous nursing intervention. Child care for purposes of this section means the provision of supervision, protection, and meeting the basic needs of children, who are not related to the primary caregivers, for three (3) or more hours a day, but less than twenty-four (24) hours a day. As part of the continuum of care for medically dependent children, the center provides a triad of medically necessary services: skilled nursing care, developmental programming, and parental training. Prescribed child care (PCCC) provides a less restrictive alternative to hospitalization and reduces the isolation often experienced by the homebound, medically dependent child and family. The purpose of prescribed childcare is health care, but does not exclude other services.

(62) Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(63) 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.

(64) 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 child's health care needs. Such availability shall include, but not be limited to, availability by telephone.

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

(66) Registered Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(67) Shall or Must. Compliance is mandatory.

(68) Social Worker. A person who has at least a bachelor's degree in Social Work or related field, and preferably, two (2) years medical social work or other community based work experience.

(Rule 1200-08-02-.01, continued)

(69) Speech Pathologist. A person currently licensed as such by the Tennessee Board of Communications Disorders and Sciences.

(70) 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.

(71) 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.

(72) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(73) Toddler. A child who is sixteen (16) months through thirty (30) months of age.

(74) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the child.

~~(75) 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.~~

(75) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 1, 1992; effective May 16, 1992. Amendment filed January 6, 1995; effective March 22, 1995. Repeal filed March 18, 2000; effective May 30, 2000. New rule filed June 13, 2002; effective August 27, 2002. Amendment filed May 16, 2006; effective July 30, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-02-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any Prescribed Child Care Center (PCCC) without having a license. A license shall be issued only to the applicant named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the PCCC.

(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, with the exception of the U.S. Government, the State of Tennessee or local government, 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.

(Rule 1200-08-02-.09, continued)

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

(4) Waste must be stored in a manner and location which afford protection from animals precipitation, wind, and direct sunlight, do not present a safety hazard, do not provide a breeding place or food source for insects or rodents and do not create a nuisance.

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

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of paragraph (4) of this rule; and

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed June 13, 2002; effective August 27, 2002.*

1200-08-02-.10 RECORDS AND REPORTS.

(1) Children's Records.

(a) The following records shall be maintained at the PCCC and made available to the Department upon request. Each child shall have a record containing the following information:

1. A current information form which includes the child's name, date of birth, name of parent(s), child and parent's home address, parent's business address, phone numbers, work hours, social history, and the name and address (home and business or school) of a responsible person to contact in an emergency if parent(s) cannot be located promptly;

2. Name, address and telephone number of a physician to call in case of an emergency;

3. Written consent of parent(s) regarding emergency medical care;

4. A transportation plan, including to whom the child will be released, and a clear policy concerning the release of the child(ren) to anyone whose behavior may place the child(ren) in immediate risk;

5. Comprehensive protocol for care specifying the goals for care and methods for goal achievement and time frame for reviewing and revising the plan;

6. A consent for treatment form signed by parent and PCCC representative;

7. A medical history for the child, including notations from visits to health care providers;

8. Before a preschool child older than eight weeks is accepted for care, he/she shall have proof of being age-appropriately immunized according to the current

(Rule 1200-08-02-.10, continued)

schedule authorized by the Tennessee Department of Health. (Children six through eight weeks of age may be enrolled before immunizations are begun.)

9. If a child has any known allergies, they shall be indicated in the child's health record. Foreign-born children must also present evidence of tuberculosis screening. (See Appendix C)

10. A copy of each infant/toddler's or preschool child's health history and immunization record, signed or stamped by a certified health care provider, shall be on file in the prescribed child care center and available to the appropriate staff. The health record shall be returned to the parent upon request when the child leaves the center.

11. Exceptions to requirements 8. and 10. of this section may be made only if:

    (i) The child's physician or the health department provides a signed and dated statement, giving a medical reason why the child should not be given a specified immunization; or

    (ii) The child's parent provides a signed written statement that such immunizations conflict with his/her religious tenets and practices.

12. Before an infant or toddler is accepted for care, the parent shall have proof of the child's physical examination within three months prior to admission, signed or stamped by a physician or health care provider. Each infant/toddler shall have on file an official health record of the first medical checkup and health history.

13. Other requirements as set forth in Appendix C shall apply.

14. Flow chart of treatments administered;

15. Concise, accurate information and initialed case notes reflecting progress toward plan goal achievement or reasons for lack of progress;

16. Documentation of nutritional management and special diets, as appropriate;

17. Documentation of physical, occupational, speech and/or other special therapies;

18. Daily attendance records for each child;

19. Written permission for field trips away from the premises; and

20. The same records shall be kept on infants/toddlers as on other children in the PCCC. In addition, each infant's/toddler's and any other non-verbal child's daily activities, including time and amount of feeding, time and amount of medication given, vital signs taken, elimination, times of diaper changes, sleep patterns, and developmental progress shall be recorded and shared with the parent(s) daily.

(b) A child's records shall be kept for one year following the child's leaving the PCCC. (The health record shall be returned upon request when the child leaves the facility.)

~~(c) Unusual incidents shall be reported to the Department within five (5) days of the occurrence of the incident. The Board shall define, identify and establish guidelines for the reporting of an event deemed to be an unusual incident. The facility shall conduct and complete a thorough investigative analysis, which shall include any necessary corrective action, of the incident within 40 days of the occurrence of the incident. The~~

(Rule 1200-08-02-.10, continued)

~~incident report and the investigative analysis report shall be recorded in a format designated by the Department. The investigative analysis report shall remain in the facility. The Department shall have access to the investigative analysis report and any other requested facility record as allowed in T. C. A. 68-11-301 et seq. Access to the investigative analysis report shall not be deemed a waiver of any privilege afforded to the facility. Failure to comply with this sub-paragraph may result in disciplinary action against the facility before the Board.~~

(2) The PCCC shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The PCCC shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the PCCC or to the health and safety of its patients and personnel; and

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

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed June 13, 2002; effective August 27, 2002.*

1200-08-02-.11 CHILD, PARENT OR RESPONSIBLE PARTY'S RIGHTS.

(1) The PCCC shall demonstrate respect and support for each child's rights. The facility insures each child receives professional and humanistic services in a manner that protects their fundamental human, civil, constitutional and statutory rights.

Policies and procedures shall be developed, approved, and maintained to ensure consistent application and communication throughout the organization.

(a) The following rights of children and parents shall apply whenever appropriate:

1. Impartial access to treatment or accommodations that are available or medically indicated regardless of race, creed, sex, national origin, or sources of payment for care.

2. Considerate, respectful care at all times and under all circumstances, with recognition of his/her personal dignity, values and beliefs.

3. Identity and professional status of individuals providing services to the child and to know who is primarily responsible for the child's care or treatment.

4. Expectation of reasonable safety insofar as family practices and environment are concerned.

5. Confidentiality of child's records.

6. Ability to voice complaints regarding care without fear of discrimination or compromising their child's future care.

7. The parent may direct a determination which encompasses the right to make choices regarding life sustaining treatment, including resuscitative services.

8. Information about fee schedules and payment policies.

9. Environment conducive to personal and informational privacy.

(b) Children shall not be abused, neglected, or administered corporal punishment.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed June 13, 2002; effective August 27, 2002.*

1200-08-02-.12 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each prescribed child care center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a child who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual children. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the child by blood, marriage, or adoption and would not be entitled to any portion of the estate of the child upon the death of the child. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent

(Rule 1200-08-02-.12, continued)

shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(Rule 1200-08-02-.12, continued)

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-02-.12(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the child lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-02-.12(16)(c) thru 1200-08-02-.12(16)(g) is reasonably available, the designated physician may make health care decisions for the child after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the child's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-02-.12, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-02-.12(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-02-.12, continued)

the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-02-.12(20) thru 1200-08-02-.12(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-02-.12(20) thru 1200-08-02-.12(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-02-.12, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-02-.12, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

(Rule 1200-08-02-.12, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed June 13, 2002; effective August 27, 2002. Repeal and new rule filed May 16, 2006; effective July 30, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-02-.13 DISASTER PREPAREDNESS.

(1) The administrator of every PCCC shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff's signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:

(a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures; and,

5. Staff functions by department and job assignment.

(b) Tornado/Severe Weather Procedures Plan shall include:

1. Staff duties by department and job assignment; and,

2. Evacuation procedures.

(c) Bomb Threat Procedures Plan (to be exercised at anytime during the year) shall include:

1. Staff duties;

2. Search team, searching the premises;

3. Notification of authorities;

4. Location of suspicious objects; and,

5. Evacuation procedures.

(d) Floods Procedures Plans, if applicable, shall include:

1. Staff duties;

2. Evacuation procedures; and

3. Safety procedures following the flood.

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

CHAPTER 1200-08-06
STANDARDS FOR NURSING HOMES

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1200-08-06-.01 DEFINITIONS.

(1) Administrator. A person currently licensed as such by the Tennessee Board of Examiners for Nursing Home Administrators.

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

(6) 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 resident to make health care decisions while having the capacity to do so. A resident 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 resident shall have the burden of proving lack of capacity.

(7) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary functions in a resident, 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 resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(8) Certified Nurse Aide or Certified Nursing Assistant. An individual who has successfully completed an approved nursing assistant training program and is registered with the department.

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

(Rule 1200-08-06-.01, continued)

(10) Competent. A resident who has 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~~11) Department. The Tennessee Department of Health.

(~~13~~12) 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.

(~~14~~13) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners. Persons exempt from licensure shall be registered with the American Dietetics Association pursuant to T.C.A. § 63-25-104.

(~~15~~14) Director of Nursing (DON). A Registered Nurse employed full time in a nursing home who satisfies the responsibilities set forth in this chapter.

(~~16~~15) Do Not Resuscitate (DNR) Order. An order entered by the resident's treating physician in the resident's medical record which states that in the event the resident 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.

(~~17~~16) 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.

(~~18~~17) 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.

(~~19~~18) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~20~~19) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

(~~21~~20) 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).

(~~22~~21) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~23~~22) Health Care Decision-maker. In the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent

(Rule 1200-08-06-.01, continued)

as specified in an advance directive, the resident's court-appointed guardian or conservator with health care decision-making authority, the resident's surrogate as determined pursuant to Rule 1200-08-06-.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.

(~~24~~23) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~25~~24) 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.

(~~26~~25) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~27~~26) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such person, and maternity care involving labor and delivery for any period of time.

(~~28~~27) Incompetent. A resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~29~~28) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~30~~29) 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.

(~~31~~30) Involuntary Transfer. The movement of a resident between nursing homes, without the consent of the resident, the resident's legal guardian, next of kin or representative.

(~~32~~31) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~33~~32) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~34~~33) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~35~~34) Medical Director. A licensed physician employed by the nursing home to be responsible for medical care in the facility.

(~~36~~35) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the resident's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(Rule 1200-08-06-.01, continued)

(~~37~~36) Medical Equipment. Equipment used for the diagnosis, treatment and monitoring of patients, including, but not limited to, oxygen care equipment and oxygen delivery systems, enteral and parenteral feeding pumps, and intravenous pumps.

(~~38~~37) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written, electronic, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to residents.

(~~39~~38) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident.

(~~40~~39) NFPA. The National Fire Protection Association.

(~~41~~40) Nurse Aide or Nursing Assistant Training Program. A specialized program approved by the Department to provide classroom instruction and supervised clinical experience for individuals who wish to be employed as Nurse Aides or Nursing Assistants.

(~~42~~41) Nursing Personnel. Licensed nurses and certified nurse aides who provide nursing care.

(~~43~~42) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~44~~43) 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.

(~~45~~44) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~46~~45) Personally Informing. A communication by any effective means from the resident directly to a health care provider.

(~~47~~46) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(~~48~~47) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~49~~48) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~50~~49) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(~~51~~50) 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.

(Rule 1200-08-06-.01, continued)

(~~52~~51) Program Coordinator. A registered nurse who possesses a minimum of two years nursing experience with at least one year in long term care and is responsible for ensuring that the requirements of the Nurse Aide Training Program are met.

(~~53~~52) 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~~53) 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 resident's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~55~~54) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~56~~55) Resident/Patient. Includes but is not limited to any person who is suffering from an illness or injury and who is in need of nursing care.

(~~57~~56) Secured Unit. A facility or distinct part of a facility where residents are intentionally denied egress by any means.

(~~58~~57) Shall or Must. Compliance is mandatory.

(~~59~~58) Social Worker. In a facility with more than 120 beds a qualified social worker is an individual with:

(a) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and,

(b) One year of supervised social work experience in a health care setting working directly with individuals.

(~~60~~59) Speech Therapist. A person currently licensed as such by the Tennessee Board of Communication Disorders and Sciences.

(~~61~~60) 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.

(~~62~~61) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board.

(~~63~~62) 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.

(~~64~~63) Surrogate. An individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident.

(~~65~~64) Survey. An on-site examination by the department to determine the quality of care and/or services provided.

(~~66~~65) Transfer. The movement of a resident between nursing homes at the direction of a physician or other qualified medical personnel when a physician is not readily available. The

(Rule 1200-08-06-.01, continued)

term does not include movement of a resident who leaves the facility against medical advice. The term does not apply to the commitment and movement of mentally ill and mentally retarded persons, the discharge or release of a resident no longer in need of nursing home care, or a nursing home's refusal, after an appropriate medical screening, to render any medical care on the grounds that the person does not have a medical need for nursing home care.

(~~67~~66) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.

(~~68~~67) Treating Physician. The physician selected by or assigned to the resident and who has the primary responsibility for the treatment and care of the resident. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."

~~(69) 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.~~

(68) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(70) 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.~~

~~(71) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-234, 68-11-1802, and 71-6-121.* ***Administrative History:*** *Original rule filed March 27, 1975; effective April 25, 1975. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed April 10, 2000; effective June 24, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed September 21, 2005; effective December 5, 2005. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed July 18, 2007; effective October 1, 2007.*

1200-08-06-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local governmental unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any nursing home without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the nursing home.

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

(Rule 1200-08-06-.05, continued)

(12) When a resident is transferred, a copy of the clinical summary shall, with consent of the resident, be sent to the nursing home that will continue the care of the resident.

(13) Where an involuntary transfer is proposed, in addition to any other relevant factors, the following factors shall be taken into account:

(a) The traumatic effect on the resident.

(b) The proximity of the proposed nursing home to the present nursing home and to the family and friends of the resident.

(c) The availability of necessary medical and social services at the proposed nursing home.

(d) Compliance by the proposed nursing home with all applicable Federal and State regulations.

(14) When the attending physician has ordered a resident transferred or discharged, but the resident or a representative of the resident opposes the action, the nursing home shall counsel with the resident, the next of kin, sponsor and representative, if any, in an attempt to resolve the dispute and shall not transfer the resident until such counseling has been provided. No involuntary transfer or discharge shall be made until the nursing home has first informed the department and the area long-term care ombudsman. Unless a disaster occurs on the premises or the attending physician orders the transfer as a medical emergency (due to the resident's immediate need for a higher level of care) no involuntary transfer or discharge shall be made until five (5) business days after these agencies have been notified, unless they each earlier declare that they have no intention of intervening.

(15) Except when the Board has revoked or suspended the license, a nursing home which intends to close, cease doing business, or reduce its licensed bed capacity by ten percent (10%) or more shall notify both the department and the area long-term care ombudsman at the earliest moment of the decision, but not later than thirty (30) days before the action is to be implemented. The facility shall establish a protocol, subject to the department's approval, for the transfer or discharge of the residents. Should the nursing home violate the provisions of this paragraph, the department shall request the Attorney General of the State of Tennessee to intervene to protect the residents, as is provided by T.C.A. § 68-11-213(a).

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, 68-11-257, and 71-6-121.* ***Administrative History:*** *Original rule filed March 27; effective April 25, 1975. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed April 10, 2000; effective June 24, 2000. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed April 17, 2007; effective July 1, 2007.*

1200-08-06-.06 BASIC SERVICES.

(1) Performance Improvement.

(a) The nursing home must ensure that there is an effective, facility-wide performance improvement program to evaluate resident 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 related to resident care, including services furnished by a contractor, are evaluated;

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

2. Nosocomial infections and medication therapy are evaluated;

3. All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment; and

4. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program and influenza vaccination program.

(c) The nursing home must have an ongoing plan, consistent with available community and facility resources, to provide or make available services that meet the medically-related needs of its residents.

(d) The facility 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) Performance improvement program records are not disclosable, except when such disclosure is required to demonstrate compliance with this section.

(f) Good faith attempts by the performance improvement program committee to identify and correct deficiencies will not be used as a basis for sanctions.

(2) Physician Services.

(a) Policies and procedures concerning services provided by the nursing home shall be available for the admitting physicians.

(b) Residents shall be aided in receiving dental care as deemed necessary.

(c) Each nursing home shall retain by written agreement a physician to serve as a Medical Director.

(d) The Medical Director shall be responsible for the medical care in the nursing home. The Medical Director shall:

1. Delineate the responsibilities of and communicate with attending physicians to ensure that each resident receives medical care;

2. Ensure the delivery of emergency and medical care when the resident's attending physician or his/her designated alternate is unavailable;

3. Review reports of all accidents or unusual incidents occurring on the premises, identifying hazards to health and safety and recommending corrective action to the administrator;

4. Make periodic visits to the nursing home to evaluate the existing conditions and make recommendations for improvements;

5. Review and take appropriate action on reports from the Director of Nursing regarding significant clinical developments;

6. Monitor the health status of nursing home personnel to ensure that no health conditions exist which would adversely affect residents; and,

7. Advise and provide consultation on matters regarding medical care, standards of care, surveillance and infection control.

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

(3) Infection Control.

(a) The nursing home must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(b) The physical environment shall be maintained in such a manner to assure the safety and well being of the residents.

1. Any condition on the nursing home 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 facility 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. Telephones shall be readily accessible and at least one (1) shall be equipped with sound amplification and shall be accessible to wheelchair residents.

4. Equipment and supplies for physical examination and emergency treatment of residents shall be available.

5. A bed complete with mattress and pillow shall be provided. In addition, resident 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.

6. Individual wash cloths, towels and bed linens must be provided for each resident. Linen shall not be interchanged from resident to resident until it has been properly laundered.

7. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.

8. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with residents shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between residents and as often as necessary to maintain them in a clean and sanitary condition. Single use, resident disposable items are acceptable but shall not be reused.

9. The facility shall have written policies and procedures governing care of residents during the failure of the air conditioning, heating or ventilation system, including plans for hypothermia and hyperthermia. When the temperature of any resident area falls below 65° F. or exceeds 85° F., or is reasonably expected to do so, the facility shall be alerted to the potential danger, and the department shall be notified.

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

(c) The administrator shall assure that an infection control program including members of the medical staff, nursing staff and administrative staff develop guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the program shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;

3. Written procedures governing the use of aseptic techniques and procedures in the facility;

4. Written procedures concerning food handling, laundry practices, disposal of environmental and resident wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A log of incidents related to infectious and communicable diseases;

6. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing, proper grooming, masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of resident care equipment and supplies; and,

7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.

(d) The administrator, the medical staff and director of nursing services must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control program 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 resident's blood for the presence of the hepatitis B virus and the HIV 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 resident's blood or other body fluid. The testing shall be performed at no charge to the resident, and the test results shall be confidential.

(f) 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;

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.

(g) All nursing homes shall adopt appropriate policies regarding the testing of residents and staff for HIV and any other identified causative agent of acquired immune deficiency syndrome.

(h) The facility shall document evidence of annual vaccination against influenza for each resident, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control most recent to the time of the vaccine. Influenza vaccination is medically contraindicated or the resident has refused the vaccine. Influenza vaccination for all residents accepting the vaccine shall be completed by November 30 of each year or within ten (10) days of the vaccine becoming available. Residents admitted after this date during the flu season and up to February 1, shall as medically appropriate, receive influenza vaccination prior to or on admission unless refused by the resident.

The facility shall document evidence of vaccination against pneumococcal disease for all residents who are 65 years of age or older, in accordance with the recommendation of the Advisory Committee on Immunization Practices of the Centers for Disease Control at the time of vaccination, unless such vaccination is medically contraindicated or the resident has refused offer of the vaccine. The facility shall provide or arrange the pneumococcal vaccination of residents who have not received this immunization prior to or on admission unless the resident refuses offer of the vaccine.

(i) 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.

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

(j) 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. Decontamination and preparation areas shall be separated.

(k) Space and facilities for housekeeping equipment and supply storage shall be provided in each service area. Storage for bulk supplies and equipment shall be located away from patient care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.

(l) The facility shall appoint a housekeeping supervisor who shall be responsible for:

1. Organizing and coordinating the facility's housekeeping service;

2. Acquiring and storing sufficient housekeeping supplies and equipment for facility maintenance; and,

3. Assuring the clean and sanitary condition of the facility to provide a safe and hygienic environment for residents and staff. Cleaning shall be accomplished in accordance with the infection control rules herein and facility policy.

(m) Laundry facilities located in the nursing home 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 facility; 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.

(n) The facility shall name an individual who is responsible for laundry service. This individual shall be responsible for:

1. Establishing a laundry service, either within the nursing home or by contract, that provides the facility 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 and procedures; and,

4. Assuring that a contract laundry service complies with all applicable infection control rules and procedures.

(4) Nursing Services.

(a) Each nursing home must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse. Each home

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

shall have a licensed practical nurse or registered nurse on duty at all times and at least two (2) nursing personnel on duty each shift.

(b) The facility must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for resident care. The Director of Nursing (DON) must be a licensed registered nurse who has no current disciplinary actions against his/her license. The DON 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 facility.

(c) The Director of Nursing shall have the following responsibilities:

1. Develop, maintain and periodically update:

   (i) Nursing service objectives and standards of practice;

   (ii) Nursing service policy and procedure manuals;

   (iii) Written job descriptions for each level of nursing personnel;

   (iv) Methods for coordination of nursing service with other resident services; and,

   (v) Mechanisms for monitoring quality of nursing care, including the periodic review of medical records.

2. Participate in selecting prospective residents in terms of the nursing services they need and nursing competencies available.

3. Make daily rounds to see residents.

4. Notify the resident's physician when medically indicated.

5. Review each resident's medications periodically and notify the physician where changes are indicated.

6. Supervise the administration of medications.

7. Supervise assignments of the nursing staff for the direct care of all residents.

8. Plan, develop and conduct monthly in-service education programs for nursing personnel and other employees of the nursing home where indicated. An organized orientation program shall be developed and implemented for all nursing personnel.

9. Supervise and coordinate the feeding of all residents who need assistance.

10. Coordinate the dietary requirements of residents with the staff responsible for the dietary service.

11. Coordinate housekeeping personnel.

12. Assure that discharge planning is initiated in a timely manner.

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

13. Assure that residents, 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 nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and certified nurse aides to provide nursing care to all residents as needed. Nursing homes shall provide a minimum of two (2) hours of direct care to each resident every day including 0.4 hours of licensed nursing personnel time. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the availability of a licensed nurse for bedside care of any resident.

(e) A registered nurse must supervise and evaluate the nursing care for each resident.

(f) The facility must ensure that an appropriate individualized plan of care is prepared for each resident with input from appropriate disciplines, the resident and/or the resident's family or the resident's representative.

(g) A registered nurse must assign the nursing care of each resident to other nursing personnel in accordance with the resident's needs and the specialized qualifications and competence of the nursing staff available.

(h) Non-employee licensed nurses who are working in the nursing home must adhere to the policies and procedures of the facility. The director of the nursing service 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.

(i) 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.

(j) There must be a facility procedure for reporting adverse drug reactions and errors in administration of drugs.

(k) When non-employees are utilized as sitters or attendants, they shall be under the authority of the nursing service and their duties shall be set forth clearly in written nursing service policies.

(l) Each resident shall be given proper personal attention and care of skin, feet, nails and oral hygiene in addition to the specific professional nursing care as ordered by the resident's physician.

(m) Medications, treatments, and diet shall be carried out as prescribed to safeguard the resident, to minimize discomfort and to attain the physician's objective.

(n) Residents shall have baths or showers at least two (2) times each week, or more often if requested by the resident.

(o) Body position of residents in bed or chair bound shall be changed at least every two (2) hours, day and night, while maintaining good body alignment. Proper skin care shall be provided for bony prominences and weight bearing parts to prevent discomfort and the development of pressure areas, unless contraindicated by physician's orders.

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

(p) Residents who are incontinent shall have partial baths each time the bed or bed clothing has been wet or soiled. The soiled or wet bed linen and the bed clothing shall be replaced with clean, dry linen and clothing immediately after being soiled.

(q) Residents shall have shampoos, haircuts and shaves as needed, or desired.

(r) Rehabilitation measures such as assisting patients with range of motion, prescribed exercises and bowel and bladder retraining programs shall be carried out according to the individual needs and abilities of the resident.

(s) Residents shall be active and out of bed except when contraindicated by written physician's orders.

(t) Residents shall be encouraged to achieve independence in activities of daily living, self-care, and ambulation as a part of daily care.

(u) Residents shall have clean clothing as needed and shall be kept free from odor.

(v) Residents' weights shall be taken and recorded at least monthly unless contraindicated by a physician's order.

(w) Physical restraints shall be checked every thirty (30) minutes and released every two (2) hours so the resident may be exercised and offered toilet access.

(x) Restraints may be applied or administered to residents only on the signed order of a physician. The signed physician's order must be for a specified and limited period of time and must document the necessity of the restraint. There shall be no standing orders for restraints.

(y) When a resident's safety or safety of others is in jeopardy, the nurse in charge shall use his/her judgment to use physical restraints if a physician's order cannot be immediately obtained. A written order must be obtained as soon as possible.

(z) Locked restraints are prohibited.

(aa) Assistance with eating shall be given to the resident as needed in order for the resident to receive the diet for good health care.

(bb) Abnormal food intake will be evaluated and recorded.

(cc) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:

1. The deceased was a resident of a nursing home;

2. The death was anticipated, and the attending physician or nursing home medical director has agreed in writing to sign the death certificate. Such agreement by the attending physician or nursing home medical director 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 nursing home in which the deceased resided.

(5) Medical Records.

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

(a) The nursing home shall comply with the Tennessee Medical Records Act, T.C.A. §§ 68-11-301, et seq.

(b) The nursing home must maintain a medical record for each resident. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The facility 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.

(c) All medical records, in 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 after which such records may be destroyed. However, in cases of residents under mental disability or minority, their complete facility records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten (10) years following the discharge of the resident, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the facility's policies and procedures, and no record may be destroyed on an individual basis.

(d) When a nursing home closes with no plans of reopening, an authorized representative of the facility may request final storage or disposition of the facility's medical records by the department. Upon transfer to the department, the facility relinquishes all control over final storage of the records and the files shall become property of the State of Tennessee.

(e) The nursing home must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.

(f) The nursing home must have a procedure for ensuring the confidentiality of resident records. Information from or copies of records may be released only to authorized individuals, and the facility must ensure that unauthorized individuals cannot gain access to or alter resident records. Original medical records must be released by the facility only in accordance with federal and state laws, court orders or subpoenas.

(g) The medical record must contain information to justify admission, support the diagnosis, and describe the resident's progress and response to medications and services.

(h) All entries must be legible, complete, dated and authenticated according to facility policy.

(i) All records must document the following:

1. Evidence of a physical examination, including a health history, performed no more than thirty (30) days prior to admission or within forty-eight (48) hours following admission;

2. Admitting diagnosis;

3. A dietary history as part of each resident's admission record;

4. Results of all consultative evaluations of the resident and appropriate findings by clinical and other staff involved in the care of the resident;

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

5. Documentation of complications, facility acquired infections, and unfavorable reactions to drugs;

6. Properly executed informed consent forms for procedures and treatments specified by facility policy, or by federal or state law if applicable, as requiring written resident consent;

7. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the resident's condition;

8. Discharge summary with disposition of case and plan for follow-up care; and,

9. Final diagnosis with completion of medical records within thirty (30) days following discharge.

(j) Electronic and computer-generated records and signature entries are acceptable.

(6) Pharmaceutical Services.

(a) The nursing home shall have pharmaceutical services that meet the needs of the residents and are in accordance with the Tennessee Board of Pharmacy statutes and rules. The medical staff is responsible for developing policies and procedures that minimize drug errors.

(b) All internal and external medications and preparations intended for human use shall be stored separately. They shall be properly stored in medicine compartments, including cabinets on wheels, or drug rooms. Such cabinets or drug rooms shall be kept securely locked when not in use, and the key must be in the possession of the supervising nurse or other authorized persons. Poisons or external medications shall not be stored in the same compartment and shall be labeled as such.

(c) Schedule II drugs must be stored behind two (2) separately locked doors at all times and accessible only to persons in charge of administering medication.

(d) Every nursing home shall comply with all state and federal regulations governing Schedule II drugs.

(e) A notation shall be made in a Schedule II drug book and in the resident's nursing notes each time a Schedule II drug is given. The notation shall include the name of the resident receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.

(f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.

(g) 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 resident. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall 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,

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

2. Signed or initialed by the prescribing practitioner according to nursing home policy.

(h) Medications not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies. No Schedule II drug shall be given or continued beyond seventy-two (72) hours without a written order by the physician.

(i) Medication administration records (MAR) shall be checked against the physician's orders. Each dose shall be properly recorded in the clinical record after it has been administered.

(j) Preparation of doses for more than one scheduled administration time shall not be permitted.

(k) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their licenses.

(l) Unless the unit dose package system is used, individual prescriptions of drugs shall be kept in the original container with the original label intact showing the name of the resident, the drug, the physician, the prescription number and the date dispensed.

(m) Legend drugs shall be dispensed by a licensed pharmacist.

(n) Any unused portions of prescriptions shall be turned over to the resident only on a written order by the physician. A notation of drugs released to the resident shall be entered into the medical record. All unused prescriptions left in a nursing home must be destroyed on the premises and recorded be a pharmacist. Such record shall be kept in the nursing home.

(7) Radiology Services. The nursing home must maintain or have available diagnostic radiologic services according to the needs of the residents. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(8) Laboratory Services. The nursing home must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the residents. The nursing home must ensure that all laboratory services provided to its residents are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA). 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.

(9) Food and Dietetic Services.

(a) The nursing home must have organized dietary services that are directed and staffed by adequate qualified personnel. A facility may contract with an outside food management company if the company has a dietitian who serves the facility on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this paragraph and provides for constant liaison with the facility medical staff for recommendations on dietetic policies affecting resident treatment. If an outside contract is utilized for management of its dietary services, the facility shall designate a full-time employee to be responsible for the overall management of the services.

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

(b) The nursing home must designate a person, either directly or by contractual agreement, 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 qualified 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 who 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 residents 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 resident and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.

(d) Menus must meet the needs of the residents.

1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the residents and must be prepared and served as prescribed.

2. Special diets shall be prepared and served as ordered.

3. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the residents.

4. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

(e) Education programs, including orientation, on-the-job training, inservice education, and continuing education shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in the use of equipment, personal hygiene, proper inspection, and the handling, preparing and serving of food.

(f) 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 nourishments shall be provided to patients with special dietary needs. A minimum of three (3) days supply of food shall be on hand.

(g) Menus shall be prepared at least one week in advance. A dietitian shall be consulted to help write and plan the menus. If any change in the actual food served is necessary, the change shall be made on the menu to designate the foods actually served to the residents. Menus of food served shall be kept on file for a thirty (30) day period.

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

(h) The dietitian or designee shall have a conference, dated on the medical chart, with each resident and/or family within two (2) weeks of admission to discuss the diet plan indicated by the physician. The resident's dietary preferences shall be recorded and utilized in planning his/her daily menu.

(i) Food shall be protected from dust, flies, rodents, unnecessary handling, droplet infection, overhead leakage and other sources of contamination whether in storage or while being prepared and served and/or transported through hallways.

(j) Perishable food shall not be allowed to stand at room temperature except during necessary periods of preparation or serving. Prepared foods shall be kept hot (140°F or above) or cold (45°F or less). Appropriate equipment for temperature maintenance, such as hot and cold serving units or insulated containers, shall be used.

(k) All nursing homes shall have commercial automatic dishwashers approved by the National Sanitation Foundation. Dishwashing machines shall be used according to manufacturer specifications.

(l) All dishes, glassware and utensils used in the preparation and serving of food and drink shall be cleaned and sanitized after each use.

(m) The cleaning and sanitizing of handwashed dishes shall be accomplished by using a three-compartment sink according to the current "U.S. Public Health Service Sanitation Manual".

(n) The kitchen shall contain sufficient refrigeration equipment and space for the storage of perishable foods.

(o) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45°F. Freezers shall be kept at a temperature not to exceed 0°F.

(p) 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) Social Work Services.

(a) Social services must be available to the resident, the resident's family and other persons significant to the resident, in order to facilitate adjustment of these individuals to the impact of illness and to promote maximum benefits from the health care services provided.

(b) Social work services shall include psychosocial assessment, counseling, coordination of discharge planning, community liaison services, financial assistance and consultation.

(c) A resident's social history shall be obtained within two (2) weeks of admission and shall be appropriately maintained.

(d) Social work services shall be provided by a qualified social worker.

(e) Facilities for social work services shall be readily accessible and shall permit privacy for interviews and counseling.

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

(11) Physical, Occupational and Speech Therapy Services.

(a) Physical therapy, occupational therapy and speech therapy shall be provided directly or through contractual agreement by individuals who meet the qualifications specified by nursing home policy, consistent with state law.

(b) A licensed physical therapist shall be in charge of the physical therapy service and a licensed occupational therapist shall be in charge of the occupational therapy service.

(c) Direct contact shall exist between the resident and the therapist for those residents that require treatment ordered by a physician.

(d) The physical therapist and occupational therapist, pursuant to a physician order, shall provide treatment and training designed to preserve and improve abilities for independent functions, such as: range of motion, strength, tolerance, coordination and activities of daily living.

(e) Therapy services shall be coordinated with the nursing service and made a part of the resident care plan.

(f) Sufficient staff shall be made available to provide the service offered.

(12) Ventilator Services.

(a) A nursing home that provides ventilator services shall meet or exceed the following minimum standards by:

(b) Ensuring a licensed respiratory care practitioner as defined by Tennessee Code Annotated Section 63-27-102(7), shall be physically present at the facility twenty four (24) hours per day, seven (7) days per week to provide:

1. ventilator care;

2. administration of medical gases;

3. administration of aerosol medications; and

4. diagnostic testing and monitoring of life support systems;

(c) Ensuring that an appropriate individualized plan of care is prepared for each patient requiring ventilator services. The plan of care shall be developed with input and participation from a pulmonologist or a physician with experience in ventilator care;

(d) Ensuring that admissions criteria is established to ensure the medical stability of ventilator-dependent patients prior to transfer from an acute care setting;

(e) Ensuring that Arterial Blood Gas (ABG) is readily available in order to document the patient's acid base status and/or End Tidal Carbon Dioxide (etCOs) and whether continuous pulse oximetry measurements should be performed in lieu of ABG studies;

(f) Ensuring that an audible, redundant external alarm system is located outside of each ventilator-dependent patient's room for the purpose of alerting caregivers of patient disconnection, ventilator disconnection or ventilator failure;

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

(g) Ensuring that the nursing home is equipped with emergency suction equipment and an adequate number of Ambu bags for manual ventilation;

(h) Ensuring that ventilator equipment is connected to electrical outlets connected to back-up generator power;

(i) Ensuring that ventilators are equipped with battery back-up systems;

(j) Ensuring that the nursing home is equipped to employ the use of current ventilator technology consistent with meeting patients' needs for mobility and comfort; and

(k) Ensuring that a back-up ventilator is available at all times.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 27, 1975; effective April 25, 1975. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Amendment filed March 13, 1986; effective April 12, 1986. Amendment filed January 29, 1991; effective March 15, 1991. Amendment filed December 29, 1992; effective February 15, 1993. Amendment filed June 15, 1993; effective July 30, 1993. Amendment filed April 17, 1996; effective July 1, 1996. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed January 31, 2000; effective April 15, 2000. Amendment filed March 29, 2000; effective June 12, 2000. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed September 4, 2003; effective November 18, 2003. Amendment filed September 21, 2005; effective December 5, 2005. Amendment filed July 18, 2007; effective October 1, 2007.*

1200-08-06-.07 SPECIAL SERVICES: ALZHEIMER'S UNITS. Structurally distinct parts of a nursing home may be designated as special care units for ambulatory residents with dementia or Alzheimer's Disease and related disorders. Such units shall be designed to encourage self-sufficiency, independence and decision-making skills, and may admit residents only after the unit is found to be in compliance with licensure standards and upon final approval by the department. Units which hold themselves out to the public as providing specialized Alzheimer's services shall comply with the provisions of T.C.A. § 68-11-1404 and shall be in compliance with the following minimum standards:

(1) In order to be admitted to the special care unit:

(a) A diagnosis of dementia must be made by a physician. The specific etiology causing the dementia shall be identified to the best level of certainty prior to admission to the special care unit; and,

(b) The need for admission must be determined by an interdisciplinary team consisting at least of a physician experienced in the management of residents with Alzheimer's Disease and related disorders, a social worker, a registered nurse and a relative of the resident or a resident care advocate.

(2) Special care units shall be separated from the remaining portion of the nursing home by a locked door and must have extraordinary and acceptable fire safety features and policies which ensure the well being and protection of the residents.

(3) The residents must have direct access to a secured, therapeutic outdoor area. This outdoor area shall be designed and maintained to facilitate emergency evacuation.

(4) There must be limited access to the designated unit so that visitors and staff do not pass through the unit to get to other areas of the nursing home.

(5) Each unit must contain a designated dining/activity area which shall accommodate 100% seating for residents.

1200-08-06-.11 RECORDS AND REPORTS.

(1) The nursing home shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(2) 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;~~

~~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;~~

(Rule 1200-08-06-.11, continued)

~~(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:~~

~~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.~~

(Rule 1200-08-06-.11, continued)

~~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.~~

~~(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.~~

(Rule 1200-08-06-.11, continued)

~~(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.~~

(2) The nursing home shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The nursing home shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the nursing home or to the health and safety of its patients and personnel; and

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

(~~3~~4) The nursing home shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and findings, if any; and,

(h) Maintenance records of all safety and patient care equipment.

1. Routine maintenance shall be administered according to the manufacture's recommended maintenance for the above equipment.

(Rule 1200-08-06-.11, continued)

2. Ensure that facility staff or contract personnel are appropriately trained to conduct safety and patient care equipment inspections.

(45) A yearly statistical report, the "Joint Annual Report of Nursing Homes", shall be submitted to the Department. The forms are mailed to each nursing home by the Department each year. The forms shall be completed and returned to the Department as requested.

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, 68-11-213, and 68-11-804.* ***Administrative History:*** *Original rule filed March 27, 1975; effective April 25, 1997. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Amendment filed March 13, 1986; effective April 12, 1986. Amendment filed December 29, 1993; effective February 15, 1993. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed September 4, 2003; effective November 18, 2003. Amendment filed April 17, 2007; effective July 1, 2007.*

(Rule 1200-08-06-.12, continued)

on a separate list which shall be available for inspection by the department and by the area long-term care ombudsman.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-901, and 68-11-902.* ***Administrative History:*** *Original rule filed March 27, 1975; effective April 25, 1975. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Amendment filed May 24, 2985; effective June 23, 1985. Amendment filed March 13, 1986; effective April 12, 1986. Amendment filed October 22, 1987; effective December 6, 1987. Amendment filed May 10, 1990; effective June 24, 1990. Amendment filed March 9, 1992; effective April 23, 1992. Amendment filed March 10, 1995; effective May 24, 1995. Amendment filed June 13, 1997; effective August 27, 1997. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed September 21, 2005; effective December 5, 2005.*

1200-08-06-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each nursing home shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the resident upon the death of the resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the resident lacks capacity, and ceases to be effective upon a determination that the resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the resident's best interest. In determining the

(Rule 1200-08-06-.13, continued)

resident's best interest, the agent shall consider the resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a resident who is an adult or emancipated minor if and only if:

1. the resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a resident who lacks capacity, the resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the resident is receiving health care.

(Rule 1200-08-06-.13, continued)

(d) The resident's surrogate shall be an adult who has exhibited special care and concern for the resident, who is familiar with the resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the resident's spouse, unless legally separated;

2. the resident's adult child;

3. the resident's parent;

4. the resident's adult sibling;

5. any other adult relative of the resident; or

6. any other adult who satisfies the requirements of 1200-08-06-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the resident shall be eligible to serve as the resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the resident or in accordance with the resident's best interests;

2. The proposed surrogate's regular contact with the resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-06-.13(16)(c) thru 1200-08-06-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-06-.13, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the resident's best interest. In determining the resident's best interest, the surrogate shall consider the resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the resident may make all health care decisions for the resident that the resident could make on the resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a resident upon a decision of the surrogate only when the designated physician and a second independent physician certify in the resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-06-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the resident's individual instructions and may not revoke the resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-06-.13, continued)

the resident's current clinical record and communicate the determination to the resident, if possible, and to any person then authorized to make health care decisions for the resident.

(19) Except as provided in 1200-08-06-.13(20) thru 1200-08-06-.13(22), a health care provider or institution providing care to a resident shall:

(a) comply with an individual instruction of the resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the resident; and

(b) comply with a health care decision for the resident made by a person then authorized to make health care decisions for the resident to the same extent as if the decision had been made by the resident while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the resident or to a person then authorized to make health care decisions for the resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-06-.13(20) thru 1200-08-06-.13(22) shall:

(a) promptly so inform the resident, if possible, and any person then authorized to make health care decisions for the resident;

(b) provide continuing care to the resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the resident or person then authorized to make health care decisions for the resident refuses assistance, immediately make all reasonable efforts to assist in the transfer of the resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a resident has the same rights as the resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-06-.13, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-06-.13, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the resident is an adult who is capable of making an informed decision, the resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the resident be resuscitated by the person authorized to consent on the resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

(Rule 1200-08-06-.13, continued)
Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed June 22, 1992; effective August 6, 1992. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 21, 2005; effective December 5, 2005. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-06-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) All nursing homes must have one or more on-site electrical generators which are capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators, blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells, and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source. All emergency power transfer switches shall be labeled as such. Switches affecting heat, ventilation, and all systems shall be labeled.

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the nursing home shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system (generator) shall be inspected weekly and exercised under actual load and operating temperature conditions for at least thirty (30) minutes, once each month, including automatic and manual transfer of equipment. The generator shall be exercised by trained facility staff who are familiar with the systems operation. Instructions for the operation of the systems and the manual transfer of emergency power shall be maintained with the facility's disaster preparedness plan and shall be separately identified in the plan. Records shall be maintained for all weekly inspections and monthly tests and be kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every nursing home shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills. The plan should consider the probability of the types of disasters which might occur, both natural and "man-made".

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Facilities which do not have sufficient emergency generator capacity to provide a place of refuge for residents during severe hot or cold weather emergencies shall specifically establish an emergency plan to assure a common area (dining room, hallway, or day rooms) is heated or cooled sufficiently to sustain residents during an emergency. This can be accomplished through several approaches including the installation of a transfer switch at the facility to which an emergency generator

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

CHAPTER 1200-08-10
STANDARDS FOR AMBULATORY SURGICAL TREATMENT CENTERS

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1200-08-10-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division approves an Ambulatory Surgical Treatment Center's plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Adult. An individual who has capacity and is at least 18 years of age.

(4) 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.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(6) Ambulatory surgical treatment center (ASTC). Any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures. Such facilities shall not provide beds or other accommodations for the stay of a patient to exceed twelve (12) hours duration, provided that the length of stay may be extended for an additional twelve (12) hours in the event such stay is deemed necessary by the attending physician, the facility medical director, or the anesthesiologist for observation or recovery, but in no event shall the length of stay exceed twenty-four (24) hours. Individual patients shall be discharged in an ambulatory condition without danger to the continued well-being of the patients or shall be transferred to a hospital. Excluded from this definition are the private physicians' and dentists' office practices. For the purposes of this rule, those

(Rule 1200-08-10-.01, continued)

medical and dental offices, facilities, and other settings at which surgical procedures exclusively are performed are ASTC's and not private office practices.

ASTC's must comply with the following for purposes of these regulations:

(a) surgical procedures performed must be limited to those procedures which are commonly performed on an inpatient basis in hospitals but may safely be performed in an ASTC;

(b) if anesthesia is required for a surgical procedure, it must be local, regional or general anesthesia and routinely be four (4) hours or less in duration;

(c) surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or are considered emergency or life-threatening in nature may not be performed.

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

(8) Cancer Treatment and Radiation Clinic. A facility in which the only procedures performed are diagnostic and therapeutic radiology, chemotherapy and related services.

(9) 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.

(10) 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 ventilators or respirators, 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.

(11) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(12) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

(13) Collaborative Plan. The formal written plan between the mid-level practitioners and licensed physician.

(14) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians, mid-level practitioners or nurse midwives.

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

(16) Competent. A patient who has capacity.

(Rule 1200-08-10-.01, continued)

~~(17) 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 incident,~~

~~(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.~~

(~~18~~17) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(~~19~~18) Department. The Tennessee Department of Health.

(~~20~~19) 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.

(~~21~~20) Do Not Resuscitate (DNR) order. An order entered by the patient's treating physician in the patient's medical records 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.

(~~22~~21) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(~~23~~22) 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.

(~~24~~23) 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.

(~~25~~24) Gastrointestinal Endoscopy Clinic. A facility in which the only procedures performed are those related to the gastrointestinal tract and other endoscopic procedures. This excludes laparoscopy and limits entry to major body cavities by needle aspiration only.

(~~26~~25) General Anesthesia. An induced state of unconsciousness accompanied by partial or complete loss of protective reflexes inducing the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command, and produced by a pharmacological or non-pharmacological method or a combination thereof.

(~~27~~26) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(~~28~~27) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(Rule 1200-08-10-.01, continued)

(~~29~~28) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~30~~29) 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).

(~~31~~30) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~32~~31) 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 1200-08-10-.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.

(~~33~~32) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~34~~33) 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.

(~~35~~34) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more non-related persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~36~~35) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~37~~36) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~38~~37) 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.

(~~39~~38) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~40~~39) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules and regulations.

(~~41~~40) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~42~~41) Medical emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(Rule 1200-08-10-.01, continued)

(~~43~~42) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~44~~43) Medical Staff. An organized body composed of individuals appointed by the ambulatory surgical treatment center governing board. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(~~45~~44) 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.

(~~46~~45) Mid-Level Practitioner. A registered nurse licensed in Tennessee who holds a master's degree in a clinical nursing specialty, national certification through the ANCC or American Academy of Nurse Practitioners and holds a certificate of fitness to prescribe from the Tennessee Board of Nursing.

(~~47~~46) N.F.P.A. National Fire Protection Association.

(~~48~~47) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(~~49~~48) 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.

(~~50~~49) 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.

(~~51~~50) PALS. Pediatric Advance Life Support.

(~~52~~51) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~53~~52) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~54~~53) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~55~~54) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. §63-19-107(2)(A).

(Rule 1200-08-10-.01, continued)

(~~56~~55) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(~~57~~56) 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.

(~~58~~57) 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.

(~~59~~58) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.

(~~60~~59) 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.

(~~61~~60) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.

(~~62~~61) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.

(~~63~~62) Shall or Must. Compliance is mandatory.

(~~64~~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.

(~~65~~64) 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~~65) Surgical Procedure. A manual or operative method performed by a licensed medical practitioner to treat diseases, injuries, conditions and/or deformities. (As related to pregnancy termination, surgical procedure excludes, but is not limited to, PAP smear or vaginal examinations, ultrasounds, amniocentesis, intramuscular injections.)

(~~67~~66) Surgical Technologist. A person who works under supervision to facilitate the safe and effective conduct of invasive surgical procedures. This individual is usually employed by a hospital, medical office, or surgical center and supervised during the surgical procedure according to institutional policy and procedure to assist in providing a safe operating room environment that maximizes patient safety by performing certain tasks including, but not limited to:

(a) Preparation of the operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments, and equipment using sterile technique;

(b) Preparation of the operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely; and

(c) Passing instruments, equipment or supplies to a surgeon, sponging or suctioning an operative site, preparing and cutting suture material, holding retractors, transferring but

(Rule 1200-08-10-.01, continued)

not administering fluids or drugs, assisting in counting sponges, needles, supplies, and instruments, and performing other similar tasks as directed during a surgical procedure.

(~~68~~67) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~69~~68) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(~~70~~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.

~~(71) 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.~~

(70) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(72) 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.~~

~~(73) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-216, 68-11-224, 68-11-1802, 68-57-101, 68-57-102 and 68-57-105.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed August 10, 1982; effective September 9, 1982. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Amendment filed March 12, 1993; effective April 26, 1993. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed May 20, 2004; effective August 3, 2004. Amendments filed September 9, 2005; effective November 23, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-10-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any ASTC as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30. The license shall be posted in a conspicuous place in the ASTC.

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

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

(Rule 1200-08-10-.04, continued)

(f) 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.

(22) The ASTC shall ensure a framework for addressing issues related to care at the end of life.

(23) The ASTC shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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

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

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

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

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

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

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268 and 71-6-121.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed September 9, 2005; effective November 23, 2005. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-10-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Every person admitted for care or treatment to any ASTC shall be under the supervision of a physician licensed to practice in Tennessee. The name, address and telephone number of the physician attending the patient shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to an ASTC by a dentist or podiatrist licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.

(Rule 1200-08-10-.05, continued)

(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) 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.

(5) 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 ASTC protocol or rules.

(6) Each ASTC must have a written transfer agreement with a local hospital.

(7) The ASTC shall develop a patient referral system both for referrals within the facility and other health care providers.

(8) The ASTC shall have available a plan for emergency transportation to a licensed local hospital.

(9) The facility must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The facility's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician; and

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-ambulatory surgical treatment center environment.

(10) A discharge plan is required on every patient, even if the discharge is to home.

(11) The facility must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(12) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

(Rule 1200-08-10-.05, continued)
1200-08-10-.06 BASIC SERVICES.

(1) Surgical Services.

(a) Facilities restricted in services they provide, e.g. those that restrict services to radiation therapy or use of local anesthetics only, may be exempted from all or part of the requirements of this rule pertaining to laboratory services, food and dietetic services, surgical services, and anesthesia services.

(b) If the facility 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.

(c) A hospital may choose to separately license a portion of the facility as an Ambulatory Surgical Treatment Center; the licensure fee for such is not required.

(d) The organization of the surgical services must be appropriate to the scope of the services offered.

(e) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

~~(f) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.~~

(f) An ASTC may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (L.P.N.) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.

(g) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(h) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(i) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(j) Surgical technologists must:

1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or

2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(Rule 1200-08-10-.06, continued)

3. Have completed an appropriate training program for surgical technologists in the armed forces or at a CAAHEP accredited hospital or CAAHEP accredited ambulatory surgical treatment center; or

4. Successfully complete the surgical technologists LCC-ST certifying exam; or

5. Provide sufficient evidence that, prior to May 21, 2007, the person was at any time employed as a surgical technologist for not less than eighteen (18) months in the three (3) years preceding May 21, 2007 in a hospital, medical office, surgery center, or an accredited school of surgical technology; or has begun the appropriate training to be a surgical technologist prior to May 21, 2007, provided that such training is completed within three (3) years of May 21, 2007.

(k) An ASTC can petition the director of health care facilities of the department for a waiver from the provisions of 1200-08-10-.06(1)(j) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.

(l) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal.

(m) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(n) Properly executed informed consent, advance directive, and organ donation forms must be in the patient's chart before surgery, except in emergencies.

(o) Adequate equipment and supplies must be available to the operating room suites and to the post-operative care area;

1. Call-in system (OR)

2. Cardiac monitor

3. Pulse Oximeter

4. Resuscitator

5. Defibrillator

6. Aspirator

7. Tracheotomy set

(Rule 1200-08-10-.06, continued)

(p) A crash cart must be available and include at a minimum the following medication and supplies:

1. adrenalin (epinephrine) 1: 10,000 dilution; 10 ml
2. adrenalin (epinephrine) 1:1000 dilution; 1 ml
3. atropine 0.1 mg/ml
4. benadryl (diphenhydramine)
5. calcium chloride 10%; 10ml amp
6. dextrose. 50%
7. dilantin (phentoin)
8. dopamine
9. heparin
10. inderal (proprandolol)
11. isuprel
12. lanoxin (digoxin)
13. lasix (furosemide)
14 xylocaine (lidocaine)
15. magnesium sulfate 50%
16. narcan (naloxone)
17. pronestyl (procainaimide)
18. sodium bicarbonate 50 mEq/50ml
19. solu-medrol (methylprednisolone)
20. verapamil hydrochloride
21. mazicon
22. Suction devices, endotracheal tubes, laryngoscopes, etc.,
23. Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
24. Double tourniquet for the Bier block procedure.
25. Emergency intubation equipment.
26. IV solution and IV equipment.

(Rule 1200-08-10-.06, continued)

(q) At least one registered nurse shall be in the recovery area during the patient's recovery period.

(r) The operating room register must be complete and up-to-date.

(s) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

(t) The ASTC shall provide one or more surgical suites which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.

(u) Surgical suites are required to meet the same standards as hospital operating rooms, including those using general anesthesia.

(v) The ASTC shall have separate areas for waiting rooms, recovery rooms, treatment and/or examining rooms.

(2) Anesthesiology Services. Anesthesia shall be administered by:

(a) A qualified anesthesiologist;

(b) A doctor of medicine or osteopathy (other than an anesthesiologist);

(c) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(d) A certified registered nurse anesthetist (CRNA); or

(e) A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(f) After the completion of anesthesia, patients shall be constantly attended by competent personnel until responsive and able to summon aid. Each center shall maintain a log of the inspections made prior to each day's use of the anesthesia equipment. A record of all service and maintenance performed on all anesthesia machines, vaporizers and ventilators shall also be on file.

(g) When general anesthesia and/or succinylcholine are administered, the facility shall maintain thirty-six (36) ampules of dantrolene for injection on site. If dantrolene is administered, appropriate monitoring must be provided post operatively.

(h) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the Medical Staff and governing body.

(i) Any patient receiving conscious sedation shall receive:

1. continuous EKG monitoring;

2. continuous oxygen saturations;

3. serial BP monitoring at intervals no less than every 5 minutes; and

4. supplemental oxygen therapy and immediately available:

(i) ambubag;

(Rule 1200-08-10-.06, continued)

(ii) suction;

(iii) endotracheal tube; and

(iv) crash cart.

(3) Medical Staff.

(a) The ASTC shall have a medical staff organized under written by-laws that are approved by the governing body. The medical staff of the ASTC shall define a mechanism to:

1. Assure that an optimal level of professional performance is maintained;

2. Appoint independent practitioners through a defined credentialing process;

3. Apply credentialing criteria uniformly;

4. Utilize the current license, relevant training and experience, current competence and the ability to perform requested privileges in the credentialing process; and

5. Provide for participation in required committees of the facility to ensure that quality medical care is provided to the patients.

(b) Each licensed independent practitioner shall provide care under the auspices of the facility in accordance with approved privileges.

(c) Clinical privileges shall be granted based on the practitioners' qualifications and the services provided by the facility, and shall be reviewed and/or revised at least every two (2) years.

(4) Nursing Service. A licensed registered nurse (R.N.) shall be on duty at all times. Additional appropriately trained staff shall be provided as needed to ensure that the medical needs of the patients are fully met.

(a) The ASTC shall be organized under written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care and nursing services.

(b) A qualified registered nurse designated by the administrator shall be responsible for coordinating and supervising all nursing services.

(c) There shall be a sufficient staffing pattern of registered nurses to provide quality nursing care to each surgical patient from admission through discharge. Additional staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.

(d) The ASTC shall establish written procedures for emergency services which will ensure that professional staff members who have been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient in the ASTC and until the patient has been discharged.

(e) Nursing care policies and procedures shall be consistent with professionally recognized standards of nursing practice and shall be in accordance with the Nurse Practice Act of

(Rule 1200-08-10-.06, continued)

the State of Tennessee and the Association of Operating Room Nurses Standards of Practice.

(f) Staff development and training shall be provided to the nursing staff and other ancillary staff in order to maintain and improve knowledge and skills. The educational/training program shall be planned, documented and conducted on a continuing basis. There shall be at least appropriate training on equipment, safety concerns, infection control and emergency care on an annual basis.

(5) Pharmaceutical Services. The ASTC must provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.

(6) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.

(7) Radiological Services. The ASTC shall provide within the facility, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical treatment center.

(a) If radiological services are provided by facility staff, the services shall be maintained free of hazards for patients and personnel.

(b) New installations of radiological equipment, and subsequent inspections for the identification of radiation hazards shall be made as specified in state and federal requirements.

(c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.

1. Personnel - The ASTC shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.

2. The use of all radiological apparatus shall be limited to personnel designated as qualified by the radiologist; and use of fluoroscopes shall be limited to physicians.

(d) If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet state and federal requirements.

(8) Laboratory Services.

(a) The ASTC shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the ASTC.

(b) Any patient terminating pregnancy in an ASTC shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.

(Rule 1200-08-10-.06, continued)

(9) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.

(10) Environmental Services.

(a) The facility shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.

(b) The facility shall develop policies and procedures that address:

1. Safety;

2. Security;

3. Control of hazardous materials and waste;

4. Emergency preparedness;

5. Life safety;

6. Medical equipment; and,

7. Utility systems.

(c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.

(d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.

(e) Safety issues shall be addressed and resolved.

(f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.

(g) The building and grounds shall be suitable to services provided and patients served.

(11) Medical Records.

(a) The ASTC shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.

(b) A medical record shall be maintained for each person receiving medical care provided by the ASTC and shall include:

1. Patient identification;

2. Name of nearest relative or other responsible agent;

3. Identification of primary source of medical care;

4. Dates and times of visits;

5. Signed informed consent;

(Rule 1200-08-10-.06, continued)

6. Pertinent medical history;

7. Diagnosis;

8. Physician examination report;

9. Anesthesia records of pertinent preoperative and postoperative reports including preanesthesia evaluation, type of anesthesia, technique and dosage used;

10. Operative report;

11. Discharge summary, including instructions for self care and instructions for obtaining postoperative emergency care;

12. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,

13. X-ray reports.

(c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68, 68-11-209, 68-11-216, 68-57-101, 68-57-102, ~~and~~ 68-57-104, and 68-57-105.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-10-.07 RESERVED.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 4, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-08-10-.08 BUILDING STANDARDS.

(1) The ambulatory surgical treatment center must be constructed, arranged, and maintained to ensure the safety of the patient.

(2) The condition of the physical plant and the overall ambulatory surgical treatment center environment must be developed and maintained in such a manner that the safety and well-being of residents are assured.

(3) No ambulatory surgical treatment center shall hereafter be constructed, nor shall major alterations be made to existing ambulatory surgical treatment centers, or change in an ambulatory surgical treatment center type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ambulatory surgical treatment center is licensed or before any alteration or expansion of a licensed ambulatory surgical treatment center can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications

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

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 disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks 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 a 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) The 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 subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious wastes 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, be constructed of easily cleanable material and be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed September 9, 2005; effective November 23, 2005.*

1200-08-10-.11 RECORDS AND REPORTS.

(1) The Joint Annual Report of Ambulatory Surgical Treatment Centers shall be filed with the department. The forms are furnished and mailed to each ASTC by the department each year and the forms must be completed and returned to the department as required.

(Rule 1200-08-10-.11, continued)

(2) The facility shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(3) The ASTC shall report to the department each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of an ASTC's license.

~~(4) 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;~~

~~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;~~

(Rule 1200-08-10-.11, continued)

~~(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:~~

~~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.~~

(Rule 1200-08-10-.11, continued)

~~(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.~~

~~(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~~

(Rule 1200-08-10-.11, continued)

~~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) The ASTC shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(5) The ASTC shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ASTC or to the health and safety of its patients and personnel; and

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

(~~5~~6) The ASTC shall retain legible copies of the following records and reports which shall be retained in the facility, shall be maintained in a single file, and shall be made available for inspection during normal business hours to any patient who requests to view them for thirty-six (36) months following their issuance:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(Rule 1200-08-10-.11, continued)

(f) Federal Health Care Financing Administration surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and finding, if any; and,

(i) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-10-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

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

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

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The ambulatory surgical treatment center must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in the decision making of all aspects of their care.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed September 9, 2005; effective November 23, 2005.*

1200-08-10-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each ambulatory surgical treatment center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(Rule 1200-08-10-.13, continued)

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

(Rule 1200-08-10-.13, continued)

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-10-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-10-.13(16)(c) thru 1200-08-10-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except

(Rule 1200-08-10-.13, continued)

that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-10-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-10-.13(20) thru 1200-08-10-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(Rule 1200-08-10-.13, continued)

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-10-.13(20) thru 1200-08-10-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(Rule 1200-08-10-.13, continued)

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(Rule 1200-08-10-.13, continued)

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed June 22, 1992; effective August 6, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 9, 2005; effective November 23, 2005. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-10-.14 DISASTER PREPAREDNESS.

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

CHAPTER 1200-08-11
STANDARDS FOR HOMES FOR THE AGED

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1200-08-11-.01 DEFINITIONS.

(1) Activities of Daily Living (ADL's). Those personal functional activities which indicate an individual's independence in eating, dressing, personal hygiene, bathing, toileting, and moving from one place to another.

(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) Aged. A person who is fifty-five (55) years of age or older.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(6) Ambulatory resident. A resident who is physically and mentally capable under emergency conditions of finding a way to safety without physical assistance from another person. An ambulatory resident may use a cane, wheelchair or other supportive device and may require verbal prompting.

(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 resident to make health care decisions while having the capacity to do so. A resident 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 resident shall have the burden of proving lack of capacity.

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

(Rule 1200-08-11-.01, continued)

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

~~(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~~11) Department. The Tennessee Department of Health.

(~~13~~12) 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 designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~14~~13) 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.

(~~15~~14) Emergency. Any situation or condition which presents an imminent danger of death or serious physical or mental harm to residents.

(~~16~~15) 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.

(~~17~~16) Evacuation Capability. The ability to either evacuate the building or move to a point of safety.

(~~18~~17) Guardian. A judicially appointed guardian of conservator having authority to make a health care decision

(~~19~~18) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(~~20~~19) 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)

(~~21~~20) Health care decision. Consent, refusal or consent or withdrawal of consent to health care.

(~~22~~21) Health Care Decision-maker. In the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive, the resident's court-appointed guardian or conservator with healthcare decision-making authority, the resident's surrogate as determined pursuant to Rule 1200-08-11-.12 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.

(~~23~~22) Health Care Institution. A health care institution as defined in T.C.A. 68-11-1602.

(Rule 1200-08-11-.01, continued)

(~~24~~23) Health Care Provider A person who si 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.

(~~25~~24) Holding Out to the Public. Advertising or soliciting the public through the use of personal, telephone, mail or other forms of communication to provide information about services provided by the facility.

(~~26~~25) Home for the Aged. A home represented and held out to the general public as a home which accepts primarily aged persons for relatively permanent, domiciliary care with primarily being defined as 51% or more of the population of the home for the aged. It provides room, board and personal services to four (4) or more nonrelated persons. The term home includes any building or part thereof which provides services as defined in these rules.

(~~27~~26) Home for the Aged Resident. A person who is ambulatory and who requires permanent, domiciliary care but who will be transferred to a licensed hospital, licensed nursing home or licensed assisted care living facility when health care services are needed which must be provided in such other facilities.

(~~28~~27) Incompetent. A resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~29~~28) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~30~~29) 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.

(~~31~~30) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~32~~31) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~33~~32) Medically Inappropriate Treatment Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident

(~~34~~33) N.F.P.A. The National Fire Protection Association.

(~~35~~34) 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~~35) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency or instrumentality, or any other legal or commercial entity.

(Rule 1200-08-11-.01, continued)

(~~37~~36) Personal Services. Those services that are rendered to residents who need supervision or assistance in activities of daily living. Personal services must include protective care of the resident, responsibility for the safety of the resident when in the facility, daily awareness of the resident's whereabouts and the ability and readiness to intervene if crises arise. Personal services do not include nursing or medical care.

(~~38~~37) Personally Informing. A communication by any effective means from the resident directly to a health care provider.

(~~39~~38) 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

(~~40~~39) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency services personnel providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~41~~40) 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 resident's health care needs. Such availability shall include, but not limited to, availability by telephone.

(~~42~~41) Responsible Attendant. The person designated by the licensee who remains awake to provide personal services to the residents. In the absence of the licensee, the responsible attendant is responsible for ensuring the home complies with all rules and regulations.

(~~43~~42) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(~~44~~43) Shall or Must. Compliance is mandatory.

(~~45~~44) 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.

(~~46~~45) Supervising Heath Care Provider. The designated physician or, if there is no designated physician ot the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~47~~46) Surrogate. An individual, other that a resident's agent or guardian, authorized to make a health care decision for the resident.

(~~48~~47) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.

~~(49) 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.~~

(48) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(50) 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 1200-08-11-.01, continued)

~~(51) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed June 21, 1979; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Amendment filed January 30, 1992; effective March 15, 1992. Amendment filed December 7, 1993; effective February 20, 1994. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003.Amendment filed September 8, 2006; effective November 22, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 23, 2007; effective May 9, 2007*

1200-08-11-.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 for the aged 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. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.

(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 based on the number of beds as follows:

1.	Less than 6 beds	$ 300.00
2.	6 to 24 beds, inclusive	$ 800.00
3.	25 to 49 beds, inclusive	$ 1,000.00
4.	50 to 74 beds, inclusive	$ 1,200.00
5.	75 to 99 beds, inclusive	$ 1,400.00
6.	100 to 124 beds, inclusive	$ 1,600.00
7.	125 to 149 beds, inclusive	$ 1,800.00
8.	150 to 174 beds, inclusive	$ 2,000.00
9.	175 to 199 beds, inclusive	$ 2,200.00

For homes for the aged of two hundred (200) beds or more the fee shall be two thousand four hundred dollars ($2,400.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal 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. Residents shall not be admitted to the home until a license has been issued.

(Rule 1200-08-11-.09, continued)

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.*

1200-08-11-.10 RECORDS AND REPORTS.

(1) 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 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;

(Rule 1200-08-11-.10, continued)

(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.

~~(2) 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;~~

~~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;~~

(Rule 1200-08-11-.10, continued)

~~(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:~~

~~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~~

(Rule 1200-08-11-.10, continued)

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 1200-08-11-.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.~~

(2) The RHA shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The RHA shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ASTC or to the health and safety of its patients and personnel; and

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

(~~3~~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;

(Rule 1200-08-11-.10, continued)

(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. Amendment filed December 23, 2009; effective March 23, 2010.*

1200-08-11-.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;

(3) To refuse treatment. The resident must be informed of the consequences of that decision, and the refusal and its reason must be reported to the physician and documented in the resident's record;

(4) To have his or her file kept confidential and private. Written consent by the resident must be obtained prior to release of information except to persons authorized by law;

(5) To be fully informed of the Resident's Rights, of any policies and procedures governing resident conduct, any services available in the home and the schedule of all fees for all services ;

(6) To participate in drawing up the terms of the admission agreement, including providing for the resident's preferences for physician care, hospitalization, assisted living facility care, nursing home care, acquisition of medication, emergency plans and funeral arrangements;

(7) To be given thirty (30) days written notice prior to transfer or discharge, except when ordered by any physician because a higher level of care is required;

(8) To voice grievances and recommend changes in policies and services of the home with freedom from restraint, interference, coercion, discrimination or reprisal. The resident shall be informed of procedures for registering complaints confidentially and to voice grievances;

(9) To manage his or her personal financial affairs, including the right to keep and spend his or her own money. If the resident requests assistance from the home in managing his or her personal financial affairs, the request must be in writing and may be terminated by the resident at any time. The home must separate such monies from the home's operating funds and all other deposits or expenditures, submit a written accounting to the resident at least quarterly, and immediately return the balance upon transfer or discharge. A current copy of this report shall be maintained in the resident's file maintained by the licensee;

(10) To be treated with consideration, respect and full recognition of his or her dignity and individuality;

(11) To be accorded privacy for sleeping and for storage space for personal belongings;

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

(12) To have free access to day rooms, dining and other group living or common areas at reasonable hours and to come and go from the home, unless such access infringes upon the rights of other residents or unless the resident is admitted to the secured unit;

(13) To wear his or her own clothes, to keep and use his or her own toilet articles and personal possessions;

(14) To send and receive unopened mail;

(15) To associate and communicate privately with persons of his or her choice, including receiving visitors at reasonable hours;

(16) To participate or to refuse to participate in community activities, including cultural, educational, religious, community service, vocational and recreational activities;

(17) To not be required to perform services for the home. The resident and licensee may mutually agree, in writing, for the resident to perform certain activities or services as part of the fee for his or her stay; and,

(18) To execute, modify, or rescind a Living Will.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed June 21, 1997; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Repeal and new rule filed July 27, 2000; effective October 10, 2000.*

1200-08-11-.12 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each home for the aged shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the resident upon the death of the resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the resident lacks capacity, and ceases to be effective upon a determination that the resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the resident's best interest. In determining the resident's best interest, the agent shall consider the resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(Rule 1200-08-11-.12, continued)

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a resident who is an adult or emancipated minor if and only if:

1. the resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a resident who lacks capacity, the resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the resident is receiving health care.

(d) The resident's surrogate shall be an adult who has exhibited special care and concern for the resident, who is familiar with the resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, be given in order of descending preference for service as a surrogate to:

1. the resident's spouse, unless legally separated;

2. the resident's adult child;

3. the resident's parent;

4. the resident's adult sibling;

(Rule 1200-08-11-.12, continued)

5. any other adult relative of the resident; or

6. any other adult who satisfies the requirements of 1200-08-11-.12(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the resident shall be eligible to serve as the resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the resident or in accordance with the resident's best interests;

2. The proposed surrogate's regular contact with the resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-11-.12(16)(c) thru 1200-08-11-.12(16)(g) is reasonably available, the designated physician may make health care decisions for the resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the resident's best interest. In determining the resident's best interest, the surrogate shall consider the resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the resident may make all health care decisions for the resident that the resident could make on the resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a resident upon a decision of the surrogate only when the designated physician and a second

(Rule 1200-08-11-.12, continued)

independent physician certify in the resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-11-.12(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the resident's individual instructions and may not revoke the resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the resident's current clinical record and communicate the determination to the resident, if possible, and to any person then authorized to make health care decisions for the resident.

(19) Except as provided in 1200-08-11-.12(20) thru 1200-08-11-.12(22), a health care provider or institution providing care to a resident shall:

(a) comply with an individual instruction of the resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the resident; and

(b) comply with a health care decision for the resident made by a person then authorized to make health care decisions for the resident to the same extent as if the decision had been made by the resident while having capacity.

(Rule 1200-08-11-.12, continued)

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the resident or to a person then authorized to make health care decisions for the resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-11-.12(20) thru 1200-08-11-.12(22) shall:

(a) promptly so inform the resident, if possible, and any person then authorized to make health care decisions for the resident;

(b) provide continuing care to the resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the resident or person then authorized to make health care decisions for the resident refuses assistance, immediately make all reasonable efforts to assist in the transfer of the resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a resident has the same rights as the resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(Rule 1200-08-11-.12, continued)

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the resident is an adult who is capable of making an informed decision, the resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that

(Rule 1200-08-11-.12, continued)

the resident be resuscitated by the person authorized to consent on the resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed June 22, 1992; effective August 6, 1992. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed September 8, 2006; effective November 22, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-11-.13 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans

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

CHAPTER 1200-08-15
STANDARDS FOR RESIDENTIAL HOSPICES

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1200-08-15-.01 DEFINITIONS.

(1) Administrator. An individual appointed by a governing body who is responsible for the day to day management of the hospice program.

(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) Bereavement Counseling. Counseling services provided to the patient's or resident's family both prior to and after the patient's or resident's death.

(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 or resident to make health care decisions while having the capacity to do so. A patient or resident 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 or resident shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient or resident, 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 or resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-15-.01, continued)

(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 or_resident assessment, responses to medications, treatments and services, and/or any changes in condition signed by a health team member who made contact with the patient or resident.

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

(13) Competent. A patient or resident 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~~15) Department. The Tennessee Department of Health.

(~~17~~16) 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~~17) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners. Persons exempt from licensure shall be registered with the American Diabetics Association pursuant to T.C.A. §63-25-204.

(~~19~~18) Do Not Resuscitate (DNR) Order. An order entered by the patient's or resident's treating physician in the patient's medical records which states that in the event the patient or resident 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.

(~~20~~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.

(~~21~~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.

(~~22~~21) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~23~~22) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(Rule 1200-08-15-.01, continued)

(~~24~~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).

(~~25~~24) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~26~~25) Health Care Decision-maker. In the case of a patient or resident who lacks capacity, the patient's or resident's health care decision-maker is one of the following: the patient's or resident's health care agent as specified in an advance directive, the patient's or resident's court-appointed guardian or conservator with health care decision-making authority, the patient's or resident's surrogate as determined pursuant to Rule 1200-08-15-.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.

(~~27~~26) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~28~~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.

(~~29~~28) HIV Resident. An individual who is in need of domiciliary care and who has been diagnosed and certified in writing by a licensed physician as being HIV (human immunodeficiency virus) positive.

(~~30~~29) Home Care Organization. As defined by T.C.A. § 68-11-201 "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.

(~~31~~30) 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.

(~~32~~31) Hospice Care Clinical Coordinator. A person identified as being responsible for the clinical management of all aspects of a hospice program. The hospice clinical coordinator must have at least one (1) year of supervisory experience in hospice or home health care and be either a licensed physician or a registered nurse.

(~~33~~32) Hospice Patient. An individual who:

(a) Has been diagnosed as terminally ill;

(b) Has been certified in writing by a physician to have an anticipated life expectancy of six (6) months or less; and,

(c) Has voluntarily requested admission to, and been accepted by a licensed hospice.

(~~34~~33) Hospice Services. A coordinated program of care, under the direction of an identifiable hospice administrator, which provides palliative and supportive medical and other services to hospice patients and their families. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week.

(Rule 1200-08-15-.01, continued)

(~~35~~34) Incompetent. A patient or resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~36~~35) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~37~~36) 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.

(~~38~~37) Involuntary Transfer. The movement of a patient or resident without the consent of the resident, the resident's legal guardian, next of kin or representative, with required notification to the appropriate agencies.

(~~39~~38) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~40~~39) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~41~~40) Licensed Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(~~42~~41) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~43~~42) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~44~~43) Medical Director. A licensed physician employed by the residential hospice to be responsible for medical care in the facility.

(~~45~~44) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's or resident's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~46~~45) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, and other written electronics, or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to patients and residents.

(~~47~~46) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or resident or other medical or surgical treatments to achieve the expressed goals of the informed patient or resident. In the case of the incompetent patient or resident, the patient's or resident's representative expresses the goals of the patient or resident.

(~~48~~47) Medical Social Services. When provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social worker or social work assistant employed by the residential hospice and under the supervision of a certified master social worker or licensed clinical social worker, and in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work

(Rule 1200-08-15-.01, continued)

with the family, utilize appropriate community resources, participate in discharge planning and in-service programs, and act as a consultant to other organization personnel.

(~~49~~48) N.F.P.A. The National Fire Protection Association.

(~~50~~49) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~51~~50) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~52~~51) 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.

(~~53~~52) 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.

(~~54~~53) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~55~~54) Personally Informing. A communication by any effective means from the patient or resident directly to a health care provider.

(~~56~~55) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(~~57~~56) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~58~~57) Physical Therapist Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~59~~58) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~60~~59) 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.

(~~61~~60) 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.

(~~62~~61) 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 or resident's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~63~~62) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(Rule 1200-08-15-.01, continued)

(~~64~~63) Residential Hospice. A licensed homelike residential facility designed, staffed and organized to provide hospice and/or HIV care services, except such services shall be provided at such residential facility rather than the patient's or resident's regular or temporary place of residence. A residential hospice shall not provide hospice and/or HIV care services to any person other than a hospice and/or HIV resident.

(~~65~~64) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~66~~65) Respiratory Therapy Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~67~~66) Respite Care. A short-term period of inpatient care provided to a hospice patient only when necessary to relieve the family members or other persons caring for the patient.

(~~68~~67) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(~~69~~68) Shall or Must. Compliance is mandatory.

(~~70~~69) Social Worker. An individual who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education and has one (1) year of social work experience in a health care setting.

(~~71~~70) 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.

(~~72~~71) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(~~73~~72) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that organization.

(~~74~~73) 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.

(~~75~~74) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~76~~75) 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.

(~~77~~76) 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 regulations.

(Rule 1200-08-15-.01, continued)

(~~78~~77) Surrogate. An individual, other than a patient's or resident's agent or guardian, authorized to make a health care decision for the patient or resident.

(~~79~~78) 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.

(~~80~~79) Transfer. The movement of a patient or resident at the direction of a physician or other qualified medical personnel when a physician is not readily available, but does not include such movement of a patient or resident who leaves the facility against medical advice.

(~~81~~80) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient or resident.

~~(82) 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.~~

(81) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(83) 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.~~

~~(84) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~85~~82) Volunteer. An individual who agrees to provide services to a hospice care patient or HIV resident and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 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 August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed November 22, 2005; effective February 5, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-15-.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 residential hospice 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 residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the residential hospice.

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

(Rule 1200-08-15-.10, continued)

(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 in 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 in 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) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall 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, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-08-15-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report" shall be submitted to the department. The forms are mailed to each residential hospice by the department each year. The forms must be completed and returned to the department as requested.

(2) The residential hospice shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(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;~~

(Rule 1200-08-15-.11, continued)

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;

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;

(Rule 1200-08-15-.11, continued)

~~(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:~~

~~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~~

(Rule 1200-08-15-.11, continued)

~~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.~~

~~(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.~~

(3) The residential hospice shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(4) The residential hospice shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the residential hospice or to the health and safety of its patients and personnel; and

(Rule 1200-08-15-.11, continued)

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

(45) The residential hospice shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and finding, if any; and,

(h) 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, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-15-.12 PATIENT/RESIDENT RIGHTS.

(1) The residential hospice shall establish and implement written policies and procedures setting forth the rights of patients and residents for the protection and preservation of dignity and individuality. Each patient and resident has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To privacy, for visits by his/her spouse or significant other;

(c) To share a room with his/her spouse or significant other;

(d) To be different in order to promote social, religious, and psychological well being;

(e) To privately talk and/or meet with and see any person;

(f) To send and receive mail promptly and unopened;

(g) To be free from mental and physical abuse. Should this right be violated, the facility must notify the Department within five (5) business days of the incident and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq;

(h) To be free from chemical and physical restraints;

Rule 1200-08-15-.12, continued)

(b) When necessary to protect and preserve the rights of the patients or residents in the facility; or

(c) When contradicted by the explicit provisions of another rule of the board.

(3) Any reduction in patients' or resident's rights must be explicit, reasonable, appropriate to the justification, the least restrictive response feasible, shall be explained to the patient or resident, and must be documented in the individual patient's or resident's record by reciting the limitation's reason and scope.

(4) Patients' and/or residents' pets and other animals utilized for pet therapy programs shall be allowed in the facility. 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.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendments filed November 22, 2005; effective February 5, 2006.*

1200-08-15-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each residential hospice shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient or resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients or residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient or resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient or resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient or resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient or resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient or resident upon the death of the patient or resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient or resident lacks capacity, and ceases to be effective upon a determination that the patient or resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(Rule 1200-08-15-.13, continued)

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient or resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's or resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's or resident's best interest. In determining the patient's or resident's best interest, the agent shall consider the patient's or resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's or resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient or resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient or resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient or resident who is an adult or emancipated minor if and only if:

(Rule 1200-08-15-.13, continued)

1. the patient or resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient or resident who lacks capacity, the patient's or resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient or resident is receiving health care.

(d) The patient's or resident's surrogate shall be an adult who has exhibited special care and concern for the patient or resident, who is familiar with the patient's or resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's or resident's spouse, unless legally separated;

2. the patient's or resident's adult child;

3. the patient's or resident's parent;

4. the patient's or resident's adult sibling;

5. any other adult relative of the patient or resident; or

6. any other adult who satisfies the requirements of 1200-08-15-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient or resident shall be eligible to serve as the patient's or resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or resident or in accordance with the patient's or resident's best interests;

2. The proposed surrogate's regular contact with the patient or resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient or resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient or resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-15-.13(16)(c) thru 1200-08-15-.13(16)(g) is reasonably

(Rule 1200-08-15-.13, continued)

available, the designated physician may make health care decisions for the patient or resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's or resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's or resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's or resident's best interest. In determining the patient's or resident's best interest, the surrogate shall consider the patient's or resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient or resident may make all health care decisions for the patient or resident that the patient or resident could make on the patient's or resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient or resident upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's or resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient or resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-15-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's or resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient or resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient or resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(Rule 1200-08-15-.13, continued)

(a) A guardian shall comply with the patient's or resident's individual instructions and may not revoke the patient's or resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient or resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient or resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's or resident's current clinical record and communicate the determination to the patient or resident, if possible, and to any person then authorized to make health care decisions for the patient or resident.

(19) Except as provided in 1200-08-15-.13(20) thru 1200-08-15-.13(22), a health care provider or institution providing care to a patient or resident shall:

(a) comply with an individual instruction of the patient or resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient or resident; and

(b) comply with a health care decision for the patient or resident made by a person then authorized to make health care decisions for the patient or resident to the same extent as if the decision had been made by the patient or resident while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or resident or to a person then authorized to make health care decisions for the patient or resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-15-.13(20) thru 1200-08-15-.13(22) shall:

(a) promptly so inform the patient or resident, if possible, and any person then authorized to make health care decisions for the patient or resident;

(b) provide continuing care to the patient or resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or resident or person then authorized to make health care decisions for the patient or resident refuses assistance, immediately make all reasonable efforts

(Rule 1200-08-15-.13, continued)

to assist in the transfer of the patient or resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient or resident has the same rights as the patient or resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient or resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient or resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person~~

(Rule 1200-08-15-.13, continued)

~~authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient or resident is an adult who is capable of making an informed decision, the patient's or resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient or resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient or resident be resuscitated by the person authorized to consent on the patient's or resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient or resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's or resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a

(Rule 1200-08-15-.13, continued)

copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient or resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed November 22, 2005; effective February 5, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-15-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) All residential hospices must have one or more on-site electrical generators, which are capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source. All emergency power transfer switches shall be labeled as such. Switches affecting heat, ventilation, and all systems shall be labeled.

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the residential hospice shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system (generator) shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month including automatic and manual transfer of equipment. The generator shall be exercised by trained facility staff who are familiar with the systems operation. Instructions for the operation of the systems and the manual transfer of emergency power shall be maintained with the facility's disaster preparedness plan and shall be separately identified in the plan. Records shall be maintained for all weekly inspections and monthly tests and be kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

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

CHAPTER 1200-08-24
STANDARDS FOR BIRTHING CENTERS

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1200-08-24-.01 DEFINITIONS.

(1) Adult. An individual who has capacity and is at least 18 years of age.

(2) 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.

(3) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(4) Birthing Center. Any institution, facility, place or building devoted exclusively or primarily to the provision of routine delivery services and postpartum care for mothers and their newborn infants.

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

(6) 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.

(7) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary functions in a patient, whether by mechanical devices, chest compression, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators 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) Certified Nurse Midwife (CNM). A registered nurse currently licensed as such by the Tennessee Board of Nursing and certified by the American College of Nurse-Midwives and qualified to deliver midwifery services.

(Rule 1200-08-24-.01, continued)

(9) Certified Professional Midwife (CPM). A North American Registry of Midwives (NARM) certified midwife, who must have midwifery skills and experience evaluated and pass written and skills examinations.

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

(11) Competent. A patient who has capacity.

~~(12) 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.~~

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

(~~14~~13) 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.

(~~15~~14) 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~~15) 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.

(~~17~~16) 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.

(~~18~~17) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~19~~18) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(~~20~~19) 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).

(~~21~~20) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~22~~21) 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

(Rule 1200-08-24-.01, continued)

decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-24-.12 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.

(~~23~~22) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~24~~23) 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.

(~~25~~24) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity. injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~26~~25) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~27~~26) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~28~~27) 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.

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

(~~30~~29) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~31~~30) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations, and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~32~~31) 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.

(~~33~~32) Member of the Professional Medical Community. A professional employed by the birthing center and on the premises at the time of a voluntary delivery.

(~~34~~33) NFPA. The National Fire Protection Association.

(~~35~~34) 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.

(Rule 1200-08-24-.01, continued)

(~~36~~35) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~37~~36) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~38~~37) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~39~~38) 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.

(~~40~~39) 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.

(~~41~~40) 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.

(~~42~~41) Routine Delivery Services. Services provided by a physician or a certified professional midwife practicing when these rules become final or a certified nurse midwife related to the normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health, promoting a family-centered approach to care and viewing pregnancy and delivery as a normal physiological process requiring limited technological and pharmacological support.

(~~43~~42) Shall or Must. Compliance is mandatory.

(~~44~~43) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified medical personnel when a physician is not readily available.

(~~45~~44) 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.

(~~46~~45) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~47~~46) 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.

(~~48~~47) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~49~~48) Transfer. The movement of a patient to a hospital at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(Rule 1200-08-24-.01, continued)

(~~50~~49) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(51) 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.~~

(50) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(52) 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.~~

~~(53) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~54~~51) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a birthing center with any birthing center employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255 and 68-11-1802.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed January 3, 2006; effective March 19, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-24-.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 birthing center 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. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.

(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 birthing center until a license has been issued. Applicants shall not hold themselves out to the public as being a birthing center until the license

(Rule 1200-08-24-.09, continued)

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. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(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, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-08-24-.10 RECORDS AND REPORTS.

(1) A report of all births, deaths and stillbirths which have occurred in the birthing center shall be filed with the local registrar in the county where the institution is located. The report shall be filed on the third (3rd) working day of each month on a form furnished by the State Registrar. The report shall state whether or not the list is complete for all events which have occurred in the facility during the preceding calendar month, and if not complete, shall show the number of events not included in the report. If no birth, death, or stillbirth occurred in the facility, the words "No Report" shall be entered on the form and forwarded to the local registrar.

(2) The Joint Annual Report, a calendar year statistical report, shall be filed with the department's Bureau of Information Resources no later than sixty (60) days following the twelve (12) months ending December 31.

(3) The birthing center shall report each case of communicable disease to the local county health officer in the mariner provided by existing regulations of the department. Repeated failure to report communicable diseases shall be cause for revocation of a facility license.

~~(4) 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;~~

(Rule 1200-08-24-.10, continued)

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;~~

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;~~

(Rule 1200-08-24-.10, continued)

~~(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:~~

~~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~~

(Rule 1200-08-24-.10, continued)

~~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.~~

~~(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) The birthing center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(5) The birthing center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the birthing center or to the health and safety of its patients and personnel; and

(Rule 1200-08-24-.10, continued)

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

(~~5~~6) The birthing center shall report information contained in the medical records of patients who have cancer or precancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(~~6~~7) The birthing center shall retain legible copies of the records and reports specified in this paragraph for the thirty-six (36) month period following their issuance. Copies of these reports shall be maintained in a single file at a location convenient to the public and, during normal business hours, they shall be promptly produced for the inspection of any person who requests to view them. Each patient and each person assuming any financial responsibility for a patient must be fully informed, before or at the time of admission, of the availability of these reports to the public, of their location within the facility, and given an 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) Fire marshal reports.

(d) Department licensure and fire safety inspections and surveys.

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any.

(f) Federal Health Care Financing Administration surveys and inspections, if any.

(g) Orders of the Commissioner or Board, if any.

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 March 31, 1998; effective June 12, 1998. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-24-.11 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department and the Tennessee Department of Human Services, Adult Protective Services;

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

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

(Rule 1200-08-24-.11, continued)

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The birthing center must have policies to govern access and duplication of the patient's record.

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

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed January 3, 2006; effective March 19, 2006.*

1200-08-24-.12 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each birthing center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent

(Rule 1200-08-24-.12, continued)

shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(Rule 1200-08-24-.12, continued)

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-24-.12(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-24-.12(16)(c) thru 1200-08-24-.12(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-24-.12, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-24-.12(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-24-.12, continued)

the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-24-.12(20) thru 1200-08-24-.12(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-24-.12(20) thru 1200-08-24-.12(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-24-.12, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-24-.12, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

(Rule 1200-08-24-.12, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815 .* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed January 3, 2006; effective March 19, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-24-.13 DISASTER PREPAREDNESS.

(1) Physical Facility and Community Emergency Plans.

(a) Every birthing center shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills.

(b) The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients to other healthcare facilities must have written agreements for emergency transfers. Their agreements may be mutual, i.e., providing for transfer either way.

(c) Copies of the plan(s), either complete or outlines, shall be available to all staff. Provisions that have security implications may be omitted from the outline versions. Familiarization information shall be included in employee orientation sessions and more detailed instructions must be included in continuing education programs. Records of orientation and education programs must be maintained for at least three (3) years.

(d) Drills of the fire safety plan shall be conducted at least once a year on each major work shift, for a minimum of three times a year for each facility. A combined drill of the other internal emergency plans shall be conducted at least once a year. The risk focus may vary by drill. Both types of drills are for the purposes of educating staff, resource determination, testing personal safety provisions and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

(e) As soon as possible, real situations that result in a response by local authorities must be documented. This includes a critique of the activation of the plan. Actual documented situations that provided educational and training value may be substituted for a drill.

(2) Emergency Planning with Local Government Authorities.

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

(b) A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-08-24-.14 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

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

CHAPTER 1200-08-25
STANDARDS FOR ASSISTED-CARE LIVING FACILITIES

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1200-08-25-.01 PURPOSE.

(1) The purpose of assisted-care living services is to:

(a) Promote the availability of appropriate residential facilities for the elderly and adults with disabilities in the least restrictive and most homelike environment;

(b) Provide assisted-care living services to residents in facilities by meeting each individual's medical and other needs safely and effectively; and

(c) Enhance the individual's ability to age in place while promoting personal individuality, respect, independence, and privacy.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 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 February 9, 1998; effective April 25, 1998. Amendment filed November 25, 1998; effective February 8, 1999. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed January 24, 2006; effective April 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.02 DEFINITIONS.

(1) "Activities of Daily Living (ADL's)" means those activities which indicate an individual's independence in eating, dressing, personal hygiene, bathing, toileting, ambulating, and medication management.

(2) "Administering medication" means the direct application of a single dose of a medication to the body of a resident by injection, inhalation, ingestion, topical application or by any other means.

(3) "Administrator" means a natural person designated by the licensee to have the authority and responsibility to manage the ACLF and who is appropriately certified as an assisted-care living facility administrator or is currently licensed in Tennessee as a nursing home administrator as required by T.C.A. §§ 63-16-101, et seq.

(Rule 1200-08-25-.02, continued)

(4) "Adult" means a person 18 years of age or older.

(5) "Ambulatory" means the resident's ability to bear weight, pivot and safely walk with the use of a cane, walker, or other mechanical supportive device with or without the minimal assistance of another person. The resident must be physically and mentally capable of self-preservation by evacuating in response to an emergency. A resident who requires a wheelchair must be capable of transferring to and propelling the wheelchair independently.

(6) "Assisted-care living facility (ACLF)" means a building, establishment, complex or distinct part thereof that accepts primarily aged persons for domiciliary care and services.

(7) "Assisted-care living facility resident" or "resident" means primarily an aged person who requires domiciliary care, and who upon admission to the facility, if not ambulatory, is capable of self-transfer from the bed to a wheelchair or similar device and is capable of propelling such wheelchair or similar device independently. Such a resident may require one or more of the following services: room and board, assistance with non-medical activities of daily living, administration of typically self-administered medications, and medical services subject to the limitations of these rules.

(8) "Assessment" means a procedure for determining the nature and extent of the problem(s) and needs of a resident or potential resident to ascertain if the ACLF can adequately address those problems, meet those needs, and secure information for the use in the development of the individual care plan.

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

(10) "Continuous nursing care" means round-the-clock observation, assessment, monitoring, supervision, or provision of nursing services that can only be performed by a licensed nurse.

(11) "Distinct part" means a unit or part thereof that is organized and operated to give a distinct type of care within the larger organization which renders other types or levels of care. "Distinct" denotes both organizational and physical separateness. A distinct part of an ACLF must be physically identifiable and be operated distinguishably from the rest of the institution. It must consist of all the beds within that unit such as a separate building, floor, wing or ward. Several rooms at one end of a hall or one side of a corridor is acceptable as a distinct part of an ACLF.

(12) "Do Not Resuscitate (DNR) Order" means a written order entered by the resident's treating physician in the resident's medical record which states that in the event the resident 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.

(13) "Emergency" means any situation or condition which presents an imminent danger of death or serious physical or mental harm to residents.

(14) "Health care" means 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).

(15) "Health care decision" means an individual's consent, refusal of consent or withdrawal of consent to health care.

(16) "Health care decision-maker" means that in the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive, the resident's court-appointed guardian or conservator with health care decision-making authority, the resident's surrogate as determined pursuant T.C.A. § 68-11-1806, or the individual's designated physician pursuant to T.C.A. § 68-11-1802(a)(4).

(17) "Infectious waste" means solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure could result in an infectious disease.

(18) "Licensed health care professional" means any health care professional currently licensed by the State of Tennessee to practice within the scope of a regulated profession, such as a nurse practitioner, registered nurse, licensed practical nurse, (nurses may be licensed or hold multistate licensure pursuant to Tennessee Code Annotated §§ 63-7-101 et seq.), dietitian, dentist, occupational therapist, pharmacist, physical therapist, physician, physician assistant, psychologist, clinical social worker, speech-language pathologist, and emergency service personnel.

(19) "Licensee" means the person, association, partnership, corporation, company or public agency to which the license is issued.

(20) "Life threatening or serious injury" means an injury requiring the resident to undergo significant diagnostic or treatment measures.

(21) "Medical record" means documentation of medical histories, nursing and treatment records, care needs summaries, physician orders, and records of treatment and medication ordered and given which must be maintained by the ACLF, regardless of whether such services are rendered by ACLF staff or by arrangement with an outside source.

(22) "Medically inappropriate treatment" means resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments that cannot be expected to achieve the expressed goals of the informed resident.

(23) "NFPA" means the National Fire Protection Association.

(24) "Patient abuse" means 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.

(25) "Person" means an individual, association, estate, trust, corporation, partnership, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(26) "Personal services" means those services rendered to residents who need supervision or assistance in activities of daily living. Personal services do not include nursing or medical care.

(Rule 1200-08-25-.02, continued)

(27) "Power of Attorney for Health Care" means the legal designation of an agent to make health care decisions for the individual granting such power under T.C.A. Title 34, Chapter 6, Part 2.

(28) "Primarily aged" means that a minimum of fifty-one percent (51%) of the population of the facility is at least sixty- two (62) years of age.

(29) "Resident sleeping unit" means a single unit providing sleeping facilities for one or more persons. Resident sleeping units can also include permanent provisions for living, eating and sanitation.

(30) "Responsible attendant" means the individual person designated by the licensee to provide personal services to the residents.

(31) "Secured unit" means a distinct part of an ACLF where the residents are intentionally denied egress by any means.

(32) "Self-administration of medication" means assistance in reading labels, opening dosage packaging, reminding residents of their medication, or observing the resident while taking medication in accordance with the plan of care.

(33) "Supervising health care provider" means the health care provider who has undertaken primary responsibility for an individual's health care.

(34) "Surrogate" means an individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident pursuant to T.C.A. § 68-11-1806.

(35) "Treating health care provider" means a health care provider directly or indirectly involved in providing health care to a resident at the time such care is needed by the resident.

(36) "Universal Do Not Resuscitate Order" means 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.

~~(37) "Unusual event" means an unexpected occurrence or accident that is unrelated to the natural course of the resident's illness or underlying condition that results in death, life threatening or serious injury to a resident. An unusual event also includes an incident resulting in the abuse of a resident.~~

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, and 68-11-210.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Amendment filed February 23, 2007; effective May 9, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.03 LICENSING REQUIREMENTS.

(1) An applicant for an ACLF license shall submit the following to the office of the Board for Licensing Health Care Facilities:

(a) A completed application on a form approved by the Board;

(b) Nonrefundable application fee;

(Rule 1200-08-25-.12, continued)

(e) Maintenance records of all safety equipment.

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, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed January 24, 2006; effective April 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.13 REPORTS.

~~(1) Unusual events shall be reported to the Department of Health by the ACLF in accordance with T.C.A. §§ 68-11-211, et seq.~~

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

(2) The ACLF shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ACLF or to the health and safety of its patients and personnel; and

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

(~~2~~3) An ACLF shall file the Joint Annual Report of Assisted Care Living Facilities with the department. The forms shall be furnished and mailed to each ACLF by the department each year and the forms must be completed and returned to the department as required.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-211.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.14 RESIDENT RIGHTS.

(1) An ACLF shall ensure at least the following rights for each resident:

(a) To be afforded privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the ACLF shall notify the department and the Tennessee Department of Human Services, Adult Protective Services at 1-888-277-8366;

(c) To refuse treatment. An ACLF must inform the resident of the consequences of that decision. The ACLF must report the resident's refusal and its reason to the resident's treating physician and it must document such in the resident's record;

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

CHAPTER 1200-08-26
STANDARDS FOR HOMECARE ORGANIZATIONS PROVIDING HOME HEALTH SERVICES

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1200-08-26-.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) Agency. A Home Care Organization providing home health services.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

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

(7) Branch Office. A location or site from which a home care organization provides home health services within a portion of the total geographic area served by the licensed organization. The branch office is part of the home care organization providing home health services and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the requirements for licensing as a home care organization providing home health services. At all times a branch office must operate solely under the name of the licensed organization.

(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

(Rule 1200-08-26-.01, continued)

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.

(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) 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.~~

(~~15~~14) Department. The Tennessee Department of Health.

(~~16~~15) 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.

(~~17~~16) 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.

(~~18~~17) 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.

(~~19~~18) 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 1200-08-26-.01, continued)

(~~20~~19) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~21~~20) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~22~~21) 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).

(~~23~~22) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~24~~23) 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 1200-08-26-.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.

(~~25~~24) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~26~~25) 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.

(~~27~~26) 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.

(~~28~~27) Home Health 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 extension of therapy services, personal care regarding nutritional needs, ambulation and exercise, and household services essential to health care at home.

(~~29~~28) Home Health Service. As defined by T.C.A. § 68-11-201, "home health service" means a service provided an outpatient by an appropriately licensed health care professional or an appropriately qualified staff member of a licensed home care organization in accordance with orders recorded by a physician, and which includes one (1) or more of the following:

(a) Skilled nursing care including part-time or intermittent supervision;

(b) Physical, occupational or speech therapy;

(c) Medical social services;

(d) Home health aide services;

(e) Medical supplies and medical appliances, other than drugs and pharmaceuticals, when provided or administered as part of or through the provision of, the services described in subparagraph (a) through (d) ; and

(Rule 1200-08-26-.01, continued)

(f) Any of the foregoing items and services which are provided on an outpatient basis under arrangements made by the home care organization at a hospital, nursing home facility or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in the individual's home, or which are furnished at such facility while the individual is there to receive any such item or service, but not including transportation of the individual in connection with any such item or service.

(g) Home health service does not include services provided in the home by a sole practice therapist, when such services are within the scope of the therapist's license and incidental to services provided by the sole practice therapist in the office. A sole practice therapist means a therapist licensed under Title 63, Chapter 13 or 17, who is in sole practice and not in a business arrangement with any other therapist or other healthcare provider. Sole practice therapists are not excluded from the requirements of professional support services.

(~~30~~29) 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~~30) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~32~~31) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~33~~32) 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.

(~~34~~33) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~35~~34) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~36~~35) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~37~~36) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~38~~37) 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.

(~~39~~38) Medical Social Services. When provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social worker or social work assistant employed by the home care organization and under the supervision of a certified master social worker or licensed clinical social worker, in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work

(Rule 1200-08-26-.01, continued)

with the family, utilize appropriate community resources, participate in discharge planning and in-service programs, and act as a consultant to other organized personnel.

(~~40~~39) 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.

(~~41~~40) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~42~~41) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~43~~42) 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.

(~~44~~43) 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.

(~~45~~44) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~46~~45) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~47~~46) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~48~~47) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~49~~48) Physician. A person currently licensed as such by the Tennessee Board of Medical Examinations or currently licensed by the Tennessee Board of Osteopathic Examination. For the purposes of defining "home health services" only, "physician" includes a podiatrist licensed under Title 63, Chapter 3, provided, that any home health service ordered is a follow-up to treatment provided to the patient by the podiatrist. A physician who is licensed to practice medicine, osteopathy or podiatry in a state contiguous to Tennessee may refer a patient residing in this state to a home care organization providing home health services duly licensed under this chapter; however, this shall not be construed as authorizing an unlicensed physician to practice medicine in violation of T.C.A. §§63-6-201, 63-9-104 or 63-3-204, and such a physician shall have previously provided treatment to that patient, and shall have had an ongoing physician-patient relationship with the person for whom the referral is to be made.

(~~50~~49) 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.

(Rule 1200-08-26-.01, continued)

(~~51~~50) 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.

(~~52~~51) 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.

(~~53~~52) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~54~~53) Respiratory Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~55~~54) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~56~~55) Shall or Must. Compliance is mandatory.

(~~57~~56) 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.

(~~58~~57) Speech Therapist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(~~59~~58) 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.

(~~60~~59) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~61~~60) 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.

(~~62~~61) 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.

(~~63~~62) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~64~~63) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(65) 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~~

(Rule 1200-08-26-.01, continued)

with the family, utilize appropriate community resources, participate in discharge planning and in-service programs, and act as a consultant to other organized personnel.

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(Rule 1200-08-26-.01, continued)

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(~~52~~51) 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.

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(~~54~~53) Respiratory Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

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(~~59~~58) 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.

(~~60~~59) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~61~~60) 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.

(~~62~~61) 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.

(~~63~~62) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~64~~63) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(65) 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~~

(Rule 1200-08-26-.10, continued)

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

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

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

(a) Isolate the area;

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

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed May 31, 2000; effective August 14, 2000.*

1200-08-26-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report of Home Care Organizations", shall be submitted to the Department. The forms are mailed to each home care organization by the Department each year. The forms must be completed and returned to the Department as requested.

~~(2) 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;~~

(Rule 1200-08-26-.11, continued)

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;~~

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;~~

(Rule 1200-08-26-.11, continued)

~~(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:~~

~~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~~

(Rule 1200-08-26-.11, continued)

~~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.~~

~~(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.~~

(2) The agency providing home health services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The agency providing home health services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

(Rule 1200-08-26-.11, continued)

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

(~~3~~4) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Department licensure and fire safety inspections and surveys;

(b) Federal Health Care Financing Administration surveys and inspections, if any;

(c) Orders of the Commissioner or Board, if any; and

(d) Comptroller of the Treasury's audit report and finding, if any.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed May 31, 2000; effective August 14, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-26-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To have appropriate assessment and management of pain;

(c) To be involved in the decision making of all aspects of their care;

(d) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;

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

(f) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record; and

(g) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The agency must have policies to govern access and duplication of the patient's record.

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

(Rule 1200-08-26-.11, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed May 31, 2000; effective August 14, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2005; effective February 15, 2006.*

1200-08-26-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each home health agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(Rule 1200-08-26-.13, continued)

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

(Rule 1200-08-26-.13, continued)

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-26-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-26-.13(16)(c) thru 1200-08-26-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate.

(Rule 1200-08-26-.13, continued)

Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-26-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-26-.13(20) thru 1200-08-26-.13(22), a health care provider or institution providing care to a patient shall:

(Rule 1200-08-26-.13, continued)

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-26-.13(20) thru 1200-08-26-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(Rule 1200-08-26-.13, continued)

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

(Rule 1200-08-26-.13, continued)

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed May 31, 2000; effective August*

(Rule 1200-08-26-.13, continued)
14, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.

1200-08-26-.14 DISASTER PREPAREDNESS.

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

(2) A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed May 31, 2000; effective August 14, 2000.*

1200-08-26-.15 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED	
Physician Orders for Scope of Treatment (POST) This is a Physician Order Sheet based on the medical conditions and wishes of the person identified at right ("patient"). Any section not completed indicates full treatment for that section. When need occurs, first follow these orders, then contact physician.	Patient's Last Name First Name/Middle Initial Date of Birth
Section A **Check One Box Only**	CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse and/or is not breathing. ☐ Resuscitate (CPR) ☐ Do Not Attempt Resuscitate (DNR/no CPR) When not in cardiopulmonary arrest, follow orders in B, C, and D.
Section B **Check One Box Only**	MEDICAL INTERVENTIONS. Patient has pulse and/or is breathing. ☐ Comfort Measures Treat with dignity and respect. Keep clean, warm, and dry. Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Do not transfer to hospital for life-sustaining treatment. Transfer only if comfort needs cannot be met in current location. ☐ Limited Additional Interventions Includes care described above. Use medical treatment, IV fluids and cardiac monitoring as indicated. Do not use intubation, advanced airway interventions, or mechanical ventilation. Transfer to hospital if indicated. Avoid intensive care. ☐ Full Treatment. Includes care above. Use intubation, advanced airway interventions mechanical ventilation, and cardioversion as indicated. Transfer to hospital if indicated. Include intensive care. Other Instructions:_____
Section C **Check One Box Only**	ANTIBIOTICS – Treatment for new medical conditions: ☐ No Antibiotics ☐ Antibiotics Other Instructions:_____

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

CHAPTER 1200-08-27
STANDARDS FOR HOMECARE ORGANIZATIONS
PROVIDING HOSPICE SERVICES

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1200-08-27-.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.

(Rule 1200-08-27-.01, continued)

Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(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~~15) Department. The Tennessee Department of Health.

(~~17~~16) 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~~17) 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~~18) 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~~19) 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 1200-08-27-.01, continued)

(~~21~~20) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~22~~21) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~23~~22) 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~~23) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~25~~24) 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 1200-08-27-.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~~25) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~27~~26) 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~~27) 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~~28) 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~~29) 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~~30) 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~~31) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~33~~32) Individual instruction. An individual's direction concerning a health care decision for the individual.

(Rule 1200-08-27-.01, continued)

(~~34~~33) 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~~34) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~36~~35) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~37~~36) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~38~~37) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~39~~38) 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~~39) 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~~40) 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~~41) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~43~~42) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~44~~43) 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~~44) 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.

(~~46~~45) 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.

(Rule 1200-08-27-.01, continued)

(~~47~~46) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~48~~47) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~49~~48) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~50~~49) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~51~~50) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~52~~51) 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~~52) 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~~53) 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~~54) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~56~~55) Respiratory Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~57~~56) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~58~~57) 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~~58) Shall or Must. Compliance is mandatory.

(~~60~~59) 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~~60) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(~~62~~61) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that religious organization.

(Rule 1200-08-27-.01, continued)

(~~63~~62) 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~~63) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~65~~64) 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~~65) 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~~66) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~68~~67) 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~~68) 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.~~

(69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(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~~70) 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. Amendment filed December 23, 2009; effective March 23, 2010.*

(Rule 1200-08-27-.01, continued)

1200-08-27-.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 writing. Licenses are not transferable or assignable and shall expire annually on June 30th. 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, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.

(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 inspection and review process.

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

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

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

(Rule 1200-08-27-.10, continued)

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

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

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

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

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

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

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

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

(a) Isolate the area;

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

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000.*

1200-08-27-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report of Home Care Organizations", shall be submitted to the Department. The forms are mailed to each home care organization by the Department each year. The forms must be completed and returned to the Department as requested.

~~(2) 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.~~

(Rule 1200-08-27-.11, continued)

~~(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;~~

~~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;~~

(Rule 1200-08-27-.11, continued)

~~(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:~~

~~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~~

(Rule 1200-08-27-.11, continued)

~~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.~~

~~(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~~

(Rule 1200-08-27-.11, continued)

~~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.~~

(2) The agency providing hospice services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The agency providing hospice services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

(~~3~~4) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Department licensure surveys;

(b) Federal Health Care Financing Administration surveys and inspections, if any;

(c) Orders of the Commissioner or Board, if any; and

(d) Comptroller of the Treasury's audit report and finding, if any.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-27-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days. Suspected abuse of a patient shall be reported immediately to the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;

(c) To have appropriate assessment and management of pain;

(d) To be involved in the decision making of all aspects of their care;

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

(f) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record; and

(g) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The agency must have policies to govern access and duplication of the patient's record.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2005; effective February 15, 2006.*

1200-08-27-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each hospice agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(Rule 1200-08-27-.13, continued)

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

(Rule 1200-08-27-.13, continued)

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-27-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-27-.13(16)(c) thru 1200-08-27-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except

(Rule 1200-08-27-.13, continued)

that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-27-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-27-.13(20) thru 1200-08-27-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(Rule 1200-08-27-.13, continued)

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-27-.13(20) thru 1200-08-27-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(Rule 1200-08-27-.13, continued)

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(Rule 1200-08-27-.13, continued)

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-27-.14 DISASTER PREPAREDNESS.

(1) All agencies shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information

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

CHAPTER 1200-08-28
STANDARDS FOR HIV SUPPORTIVE LIVING CENTERS

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1200-08-28-.01 DEFINITIONS.

(1) Administrator. An individual appointed by a governing body who is responsible for the day to day management of the HIV Supportive Living Facility.

(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) Bereavement Counseling. Counseling services provided to the individual's family and/or significant other both prior to and after the individual's death.

(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 resident to make health care decisions while having the capacity to do so. A resident 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 resident shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a resident, 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 resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-28-.01, continued)

(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 resident assessment, responses to medications, treatments and services and/or any changes in condition signed by a health professional who made contact with the resident, family or significant other.

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

(13) Competent. A resident 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~~15) Department. The Tennessee Department of Health.

(~~17~~16) 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~~17) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners.

(~~19~~18) Do Not Resuscitate (DNR) Order. An order entered by the resident's treating physician in the resident's file which states that in the event the resident 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.

(~~20~~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.

(~~21~~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.

(~~22~~21) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~23~~22) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(Rule 1200-08-28-.01, continued)

(~~24~~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).

(~~25~~24) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~26~~25) Health Care Decision-maker. In the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive, the resident's court-appointed guardian or conservator with health care decision-making authority, the resident's surrogate as determined pursuant to Rule 1200-08-28-.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.

(~~27~~26) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~28~~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.

(~~29~~28) Home Care Organization. As defined by T.C.A. § 68-11-201 "home care organizations" provides home health services, home medical equipment services or hospice services to residents on an outpatient basis in either their regular or temporary place of residence.

(~~30~~29) 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.

(~~31~~30) Incompetent. A resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~32~~31) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~33~~32) 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.

(~~34~~33) Involuntary Transfer. The movement of a resident without the consent of the resident, the resident's legal guardian, next of kin or representative, with required notification to the appropriate agencies.

(~~35~~34) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~36~~35) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~37~~36) Licensed Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(~~38~~37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(Rule 1200-08-28-.01, continued)

(~~39~~38) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~40~~39) Medical Director. A licensed physician employed by the HIV supportive living facility to be responsible for medical care in the facility.

(~~41~~40) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the resident's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~42~~41) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident.

(~~43~~42) Medical Social Services. When provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social worker or social work assistant employed by a home care organization or by contract with the facility and under the supervision of a certified master social worker or licensed clinical social worker, and in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work with the family, utilize appropriate community resources, participate in discharge planning and inservice programs, and act as a consultant to other organization personnel.

(~~44~~43) N.F.P.A. The National Fire Protection Association.

(~~45~~44) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~46~~45) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~47~~46) Palliative. The reduction or abatement of pain or troubling symptoms by appropriate coordination of all elements of the health care team to achieve needed relief of distress.

(~~48~~47) 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.

(~~49~~48) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~50~~49) Personal Care Aide. A nursing assistant or a person who can demonstrate through other education or experience that he or she is qualified to provide assistance with basic care services, including simple procedures such as feeding, personal grooming, ambulating, socializing, medication prompting, exercising and other household services essential to health care.

(Rule 1200-08-28-.01, continued)

(~~51~~50) Personally Informing. A communication by any effective means from the resident directly to a health care provider.

(~~52~~51) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(~~53~~52) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~54~~53) Physical Therapist Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~55~~54) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~56~~55) 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.

(~~57~~56) 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.

(~~58~~57) 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 resident's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~59~~58) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~60~~59) Resident. An individual who has been diagnosed with symptomatic HIV (human immunodeficiency virus) disease, who has a physician who acts as the primary care provider, and who has voluntarily requested admission to, and been accepted by a licensed residential facility.

(~~61~~60) Resident File. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, and other written electronics, or graphic data prepared, kept, made or maintained in the facility that pertains to confinement or services rendered to residents.

(~~62~~61) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~63~~62) Respiratory Therapy Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~64~~63) Respite Care. A short-term period of inpatient care provided to a hospice patient only when necessary to relieve the family members or other persons caring for the patient.

(~~65~~64) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(~~66~~65) Shall or Must. Compliance is mandatory.

(Rule 1200-08-28-.01, continued)

(~~67~~66) Social Worker. An individual who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education and has one (1) year of social work experience in a health care setting.

(~~68~~67) 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.

(~~69~~68) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(~~70~~69) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that organization.

(~~71~~70) 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.

(~~72~~71) Student. A person currently enrolled in an accredited course of study that is approved by the appropriate licensing board or equivalent body.

(~~73~~72) 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.

(~~74~~73) 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 regulations.

(~~75~~74) Surrogate. An individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident.

(~~76~~75) 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.

(~~77~~76) Transfer. The movement of a resident at the direction of a physician or other qualified or certified professionals when a physician is not readily available, but does not include such movement of a resident who leaves the facility against medical advice.

(~~78~~77) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.

~~(79) 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.~~

(Rule 1200-08-28-.01, continued)

(78) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(80) 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.~~

~~(81) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~82~~79) Volunteer. An individual who agrees to provide services to a resident, staff, significant other and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-28-.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 HIV supportive living facility 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 at the time of the original licensing. The name of the HIV supportive living facility shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the HIV supportive living facility.

(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 based on the number of beds as follows:

1.	Less than 25 beds	$ 800.00
2.	25 to 49 beds, inclusive	$ 1,000.00
3.	50 to 74 beds, inclusive	$1,200.00
4.	75 to 99 beds, inclusive	$1,400.00
5.	100 to 124 beds, inclusive	$ 1,600.00
6.	125 to 149 beds, inclusive	$ 1,800.00
7.	150 to 174 beds, inclusive	$ 2,000.00
8.	175 to 199 beds, inclusive	$ 2,200.00

(Rule 1200-08-28-.10, continued)

(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 in 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 in another state, the facility must notify in writing 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) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall 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, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000.*

1200-08-28-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report" shall be submitted to the department. The forms are mailed to each HIV supportive living facility by the department each year. The forms must be completed and returned to the department as requested.

(2) The HIV supportive living facility shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(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~~

(Rule 1200-08-28-.11, continued)

~~central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~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~~

(Rule 1200-08-28-.11, continued)

~~(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:~~

~~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~~

(Rule 1200-08-28-.11, continued)

~~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.~~

~~(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.~~

(3) The HIV supportive living facility shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(4) The HIV supportive living facility shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the HIV supportive living facility or to the health and safety of its patients and personnel; and

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

(Rule 1200-08-28-.11, continued)

(45) The HIV supportive living facility shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and finding, if any; and,

(h) 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, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-28-.12 RESIDENT RIGHTS.

(1) The HIV supportive living facility shall establish and implement written policies and procedures setting forth the rights of residents for the protection and preservation of dignity and individuality. Each resident has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To privacy, for visits by his/her spouse or significant other;

(c) To share a room with his/her spouse or significant other;

(d) To be different in order to promote social, religious, and psychological well being;

(e) To privately talk and/or meet with and see any person;

(f) To send and receive mail promptly and unopened;

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

(h) To be free from chemical and physical restraints;

(i) To meet and take part in activities of social, commercial, religious, and community groups. The administrator may refuse access to the facility to any person if that person's presence would be injurious to the health and safety of a resident or staff, or would threaten the security of the property of the resident, staff or facility;

(Rule 1200-08-28-.12, continued)

(j) To retain and use personal clothing and possessions as space permits;

(k) To be free from being required by the facility to work or perform services;

(l) To be fully informed by a physician of his/her health and medical condition. The facility shall give the resident and family/significant other the opportunity to participate in planning the resident's care and medical treatment;

(m) To have appropriate assessment and management of pain;

(n) To be involved in the decision making of all aspects of their care;

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

(p) To refuse experimental treatment and drugs. The resident's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record;

(q) To have their records kept confidential and private. Written consent by the resident must be obtained prior to release of information except to persons authorized by law. If the resident lacks capacity, written consent is required from the resident's health care decision maker. The HIV supportive living facility must have policies to govern access and duplication of the resident's record;

(r) To manage personal financial affairs. Any request by the resident for assistance must be in writing. A request for any additional person to have access to a resident's funds must also be in writing;

(s) To be told in writing before or at the time of admission about the services available in the facility, about any extra charges and charges for services not covered;

(t) To be free from discrimination because of the exercise of the right to speak and voice complaints;

(u) To exercise his/her own independent judgment by executing any documents, including admission forms; and

(v) To voice grievances and complaints and to recommend changes in policies and services to the facility staff, or outside representatives of the resident's choice. The facility shall establish a grievance procedure and fully inform the resident and family/significant other of same.

(2) The rights set forth in this section may be abridged, restricted, limited or amended only as follows:

(a) When medically contraindicated;

(b) When necessary to protect and preserve the rights of the residents in the facility; or

(c) When contradicted by the explicit provisions of another rule of the board.

(3) Any reduction in resident's rights must be explicit, reasonable, appropriate to the justification, the least restrictive response feasible, shall be explained to the resident, and must be documented in the individual resident's record by reciting the limitation's reason and scope.

(Rule 1200-08-28-.12, continued)

(4) Residents' pets and other animals utilized for pet therapy programs shall be allowed in the facility. 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.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed June 18, 2002; September 1, 2002. Amendment filed December 15, 2005; effective February 28, 2006.*

1200-08-28-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each HIV supportive living facility shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the resident upon the death of the resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the resident lacks capacity, and ceases to be effective upon a determination that the resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent

(Rule 1200-08-28-.13, continued)

shall make the decision in accordance with the resident's best interest. In determining the resident's best interest, the agent shall consider the resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a resident who is an adult or emancipated minor if and only if:

1. the resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a resident who lacks capacity, the resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the resident is receiving health care.

(Rule 1200-08-28-.13, continued)

(d) The resident's surrogate shall be an adult who has exhibited special care and concern for the resident, who is familiar with the resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the resident's spouse, unless legally separated;

2. the resident's adult child;

3. the resident's parent;

4. the resident's adult sibling;

5. any other adult relative of the resident; or

6. any other adult who satisfies the requirements of 1200-08-28-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the resident shall be eligible to serve as the resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the resident or in accordance with the resident's best interests;

2. The proposed surrogate's regular contact with the resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-28-.13(16)(c) thru 1200-08-28-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-28-.13, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the resident's best interest. In determining the resident's best interest, the surrogate shall consider the resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the resident may make all health care decisions for the resident that the resident could make on the resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a resident upon a decision of the surrogate only when the designated physician and a second independent physician certify in the resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-28-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the resident's individual instructions and may not revoke the resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-28-.13, continued)

the resident's current clinical record and communicate the determination to the resident, if possible, and to any person then authorized to make health care decisions for the resident.

(19) Except as provided in 1200-08-28-.13(20) thru 1200-08-28-.13(22), a health care provider or institution providing care to a resident shall:

(a) comply with an individual instruction of the resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the resident; and

(b) comply with a health care decision for the resident made by a person then authorized to make health care decisions for the resident to the same extent as if the decision had been made by the resident while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the resident or to a person then authorized to make health care decisions for the resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-28-.13(20) thru 1200-08-28-.13(22) shall:

(a) promptly so inform the resident, if possible, and any person then authorized to make health care decisions for the resident;

(b) provide continuing care to the resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the resident or person then authorized to make health care decisions for the resident refuses assistance, immediately make all reasonable efforts to assist in the transfer of the resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a resident has the same rights as the resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-28-.13, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-28-.13, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the resident is an adult who is capable of making an informed decision, the resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the resident be resuscitated by the person authorized to consent on the resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-28-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) If an HIV supportive living facility chooses to have one or more on-site electrical generators, they shall be capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source. All emergency power transfer switches shall be labeled as such. Switches affecting heat, ventilation, and all systems shall be labeled.

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the HIV supportive living facility shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system (generator) shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month, and shall include automatic and manual transfer of equipment. The generator shall be exercised by trained facility staff who are familiar with the systems' operation. Instructions for the operation of the systems and the manual transfer of emergency power shall be maintained with the facility's disaster preparedness plan and shall be separately identified in the plan. Records shall be maintained for all weekly inspections and monthly tests and be kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every HIV supportive living facility shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills. The plan should consider the probability of the types of disasters which might occur, both natural and "man-made".

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of residents to other health care facilities must have written agreements for emergency transfers. The agreements may be mutual, i.e. providing for transfers either way.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to all staff.

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

CHAPTER 1200-08-28
STANDARDS FOR HIV SUPPORTIVE LIVING CENTERS

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1200-08-28-.01 DEFINITIONS.

(1) Administrator. An individual appointed by a governing body who is responsible for the day to day management of the HIV Supportive Living Facility.

(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) Bereavement Counseling. Counseling services provided to the individual's family and/or significant other both prior to and after the individual's death.

(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 resident to make health care decisions while having the capacity to do so. A resident 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 resident shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a resident, 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 resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-28-.01, continued)

(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 resident assessment, responses to medications, treatments and services and/or any changes in condition signed by a health professional who made contact with the resident, family or significant other.

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

(13) Competent. A resident 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~~15) Department. The Tennessee Department of Health.

(~~17~~16) 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~~17) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners.

(~~19~~18) Do Not Resuscitate (DNR) Order. An order entered by the resident's treating physician in the resident's file which states that in the event the resident 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.

(~~20~~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.

(~~21~~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.

(~~22~~21) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~23~~22) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(Rule 1200-08-28-.01, continued)

(~~24~~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).

(~~25~~24) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~26~~25) Health Care Decision-maker. In the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive, the resident's court-appointed guardian or conservator with health care decision-making authority, the resident's surrogate as determined pursuant to Rule 1200-08-28-.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.

(~~27~~26) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~28~~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.

(~~29~~28) Home Care Organization. As defined by T.C.A. § 68-11-201 "home care organizations" provides home health services, home medical equipment services or hospice services to residents on an outpatient basis in either their regular or temporary place of residence.

(~~30~~29) 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.

(~~31~~30) Incompetent. A resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~32~~31) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~33~~32) 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.

(~~34~~33) Involuntary Transfer. The movement of a resident without the consent of the resident, the resident's legal guardian, next of kin or representative, with required notification to the appropriate agencies.

(~~35~~34) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~36~~35) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~37~~36) Licensed Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(~~38~~37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(Rule 1200-08-28-.01, continued)

(~~39~~38) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~40~~39) Medical Director. A licensed physician employed by the HIV supportive living facility to be responsible for medical care in the facility.

(~~41~~40) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the resident's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~42~~41) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident.

(~~43~~42) Medical Social Services. When provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social worker or social work assistant employed by a home care organization or by contract with the facility and under the supervision of a certified master social worker or licensed clinical social worker, and in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work with the family, utilize appropriate community resources, participate in discharge planning and inservice programs, and act as a consultant to other organization personnel.

(~~44~~43) N.F.P.A. The National Fire Protection Association.

(~~45~~44) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~46~~45) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~47~~46) Palliative. The reduction or abatement of pain or troubling symptoms by appropriate coordination of all elements of the health care team to achieve needed relief of distress.

(~~48~~47) 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.

(~~49~~48) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~50~~49) Personal Care Aide. A nursing assistant or a person who can demonstrate through other education or experience that he or she is qualified to provide assistance with basic care services, including simple procedures such as feeding, personal grooming, ambulating, socializing, medication prompting, exercising and other household services essential to health care.

(Rule 1200-08-28-.01, continued)

(~~51~~50) Personally Informing. A communication by any effective means from the resident directly to a health care provider.

(~~52~~51) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(~~53~~52) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~54~~53) Physical Therapist Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~55~~54) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~56~~55) 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.

(~~57~~56) 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.

(~~58~~57) 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 resident's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~59~~58) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~60~~59) Resident. An individual who has been diagnosed with symptomatic HIV (human immunodeficiency virus) disease, who has a physician who acts as the primary care provider, and who has voluntarily requested admission to, and been accepted by a licensed residential facility.

(~~61~~60) Resident File. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, and other written electronics, or graphic data prepared, kept, made or maintained in the facility that pertains to confinement or services rendered to residents.

(~~62~~61) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~63~~62) Respiratory Therapy Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~64~~63) Respite Care. A short-term period of inpatient care provided to a hospice patient only when necessary to relieve the family members or other persons caring for the patient.

(~~65~~64) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(~~66~~65) Shall or Must. Compliance is mandatory.

(Rule 1200-08-28-.01, continued)

(~~67~~66) Social Worker. An individual who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education and has one (1) year of social work experience in a health care setting.

(~~68~~67) 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.

(~~69~~68) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(~~70~~69) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that organization.

(~~71~~70) 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.

(~~72~~71) Student. A person currently enrolled in an accredited course of study that is approved by the appropriate licensing board or equivalent body.

(~~73~~72) 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.

(~~74~~73) 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 regulations.

(~~75~~74) Surrogate. An individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident.

(~~76~~75) 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.

(~~77~~76) Transfer. The movement of a resident at the direction of a physician or other qualified or certified professionals when a physician is not readily available, but does not include such movement of a resident who leaves the facility against medical advice.

(~~78~~77) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.

~~(79) 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.~~

(Rule 1200-08-28-.01, continued)

(78) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(80) 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.~~

~~(81) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~82~~79) Volunteer. An individual who agrees to provide services to a resident, staff, significant other and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-28-.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 HIV supportive living facility 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 at the time of the original licensing. The name of the HIV supportive living facility shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the HIV supportive living facility.

(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 based on the number of beds as follows:

1.	Less than 25 beds	$ 800.00
2.	25 to 49 beds, inclusive	$ 1,000.00
3.	50 to 74 beds, inclusive	$1,200.00
4.	75 to 99 beds, inclusive	$1,400.00
5.	100 to 124 beds, inclusive	$ 1,600.00
6.	125 to 149 beds, inclusive	$ 1,800.00
7.	150 to 174 beds, inclusive	$ 2,000.00
8.	175 to 199 beds, inclusive	$ 2,200.00

(Rule 1200-08-28-.10, continued)

(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 in 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 in another state, the facility must notify in writing 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) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall 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, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000.*

1200-08-28-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report" shall be submitted to the department. The forms are mailed to each HIV supportive living facility by the department each year. The forms must be completed and returned to the department as requested.

(2) The HIV supportive living facility shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(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~~

(Rule 1200-08-28-.11, continued)

~~central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~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~~

(Rule 1200-08-28-.11, continued)

~~(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:~~

~~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~~

(Rule 1200-08-28-.11, continued)

~~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.~~

~~(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.~~

(3) The HIV supportive living facility shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(4) The HIV supportive living facility shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the HIV supportive living facility or to the health and safety of its patients and personnel; and

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

(Rule 1200-08-28-.11, continued)

(45) The HIV supportive living facility shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and finding, if any; and,

(h) 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, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-28-.12 RESIDENT RIGHTS.

(1) The HIV supportive living facility shall establish and implement written policies and procedures setting forth the rights of residents for the protection and preservation of dignity and individuality. Each resident has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To privacy, for visits by his/her spouse or significant other;

(c) To share a room with his/her spouse or significant other;

(d) To be different in order to promote social, religious, and psychological well being;

(e) To privately talk and/or meet with and see any person;

(f) To send and receive mail promptly and unopened;

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

(h) To be free from chemical and physical restraints;

(i) To meet and take part in activities of social, commercial, religious, and community groups. The administrator may refuse access to the facility to any person if that person's presence would be injurious to the health and safety of a resident or staff, or would threaten the security of the property of the resident, staff or facility;

(Rule 1200-08-28-.12, continued)

(j) To retain and use personal clothing and possessions as space permits;

(k) To be free from being required by the facility to work or perform services;

(l) To be fully informed by a physician of his/her health and medical condition. The facility shall give the resident and family/significant other the opportunity to participate in planning the resident's care and medical treatment;

(m) To have appropriate assessment and management of pain;

(n) To be involved in the decision making of all aspects of their care;

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

(p) To refuse experimental treatment and drugs. The resident's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record;

(q) To have their records kept confidential and private. Written consent by the resident must be obtained prior to release of information except to persons authorized by law. If the resident lacks capacity, written consent is required from the resident's health care decision maker. The HIV supportive living facility must have policies to govern access and duplication of the resident's record;

(r) To manage personal financial affairs. Any request by the resident for assistance must be in writing. A request for any additional person to have access to a resident's funds must also be in writing;

(s) To be told in writing before or at the time of admission about the services available in the facility, about any extra charges and charges for services not covered;

(t) To be free from discrimination because of the exercise of the right to speak and voice complaints;

(u) To exercise his/her own independent judgment by executing any documents, including admission forms; and

(v) To voice grievances and complaints and to recommend changes in policies and services to the facility staff, or outside representatives of the resident's choice. The facility shall establish a grievance procedure and fully inform the resident and family/significant other of same.

(2) The rights set forth in this section may be abridged, restricted, limited or amended only as follows:

(a) When medically contraindicated;

(b) When necessary to protect and preserve the rights of the residents in the facility; or

(c) When contradicted by the explicit provisions of another rule of the board.

(3) Any reduction in resident's rights must be explicit, reasonable, appropriate to the justification, the least restrictive response feasible, shall be explained to the resident, and must be documented in the individual resident's record by reciting the limitation's reason and scope.

(Rule 1200-08-28-.12, continued)

(4) Residents' pets and other animals utilized for pet therapy programs shall be allowed in the facility. 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.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed June 18, 2002; September 1, 2002. Amendment filed December 15, 2005; effective February 28, 2006.*

1200-08-28-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each HIV supportive living facility shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the resident upon the death of the resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the resident lacks capacity, and ceases to be effective upon a determination that the resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent

(Rule 1200-08-28-.13, continued)

shall make the decision in accordance with the resident's best interest. In determining the resident's best interest, the agent shall consider the resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a resident who is an adult or emancipated minor if and only if:

1. the resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a resident who lacks capacity, the resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the resident is receiving health care.

(Rule 1200-08-28-.13, continued)

(d) The resident's surrogate shall be an adult who has exhibited special care and concern for the resident, who is familiar with the resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the resident's spouse, unless legally separated;

2. the resident's adult child;

3. the resident's parent;

4. the resident's adult sibling;

5. any other adult relative of the resident; or

6. any other adult who satisfies the requirements of 1200-08-28-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the resident shall be eligible to serve as the resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the resident or in accordance with the resident's best interests;

2. The proposed surrogate's regular contact with the resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-28-.13(16)(c) thru 1200-08-28-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-28-.13, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the resident's best interest. In determining the resident's best interest, the surrogate shall consider the resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the resident may make all health care decisions for the resident that the resident could make on the resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a resident upon a decision of the surrogate only when the designated physician and a second independent physician certify in the resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-28-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the resident's individual instructions and may not revoke the resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-28-.13, continued)

the resident's current clinical record and communicate the determination to the resident, if possible, and to any person then authorized to make health care decisions for the resident.

(19) Except as provided in 1200-08-28-.13(20) thru 1200-08-28-.13(22), a health care provider or institution providing care to a resident shall:

(a) comply with an individual instruction of the resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the resident; and

(b) comply with a health care decision for the resident made by a person then authorized to make health care decisions for the resident to the same extent as if the decision had been made by the resident while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the resident or to a person then authorized to make health care decisions for the resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-28-.13(20) thru 1200-08-28-.13(22) shall:

(a) promptly so inform the resident, if possible, and any person then authorized to make health care decisions for the resident;

(b) provide continuing care to the resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the resident or person then authorized to make health care decisions for the resident refuses assistance, immediately make all reasonable efforts to assist in the transfer of the resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a resident has the same rights as the resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-28-.13, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-28-.13, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the resident is an adult who is capable of making an informed decision, the resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the resident be resuscitated by the person authorized to consent on the resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-28-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) If an HIV supportive living facility chooses to have one or more on-site electrical generators, they shall be capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source. All emergency power transfer switches shall be labeled as such. Switches affecting heat, ventilation, and all systems shall be labeled.

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the HIV supportive living facility shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system (generator) shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month, and shall include automatic and manual transfer of equipment. The generator shall be exercised by trained facility staff who are familiar with the systems' operation. Instructions for the operation of the systems and the manual transfer of emergency power shall be maintained with the facility's disaster preparedness plan and shall be separately identified in the plan. Records shall be maintained for all weekly inspections and monthly tests and be kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every HIV supportive living facility shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills. The plan should consider the probability of the types of disasters which might occur, both natural and "man-made".

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of residents to other health care facilities must have written agreements for emergency transfers. The agreements may be mutual, i.e. providing for transfers either way.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to all staff.

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

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

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1200-08-29-.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 1200-08-29-.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~~11) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

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

(~~14~~13) 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.

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

(~~16~~15) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~17~~16) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

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

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

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

(d) transfer to other health care facilities.

(~~18~~17) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed legal guardian or conservator with health care decision-making authority, or the patient's surrogate as determined pursuant to Rule 1200-08-29-.13 or T.C.A. §33-3-220.

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

(~~19~~18) Home Care Organization. As defined by T.C.A. § 68-11-201, a "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(~~20~~19) 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 defied in this part, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical equipment to an individual's residence;

2. Upper and lower extremity prosthetics and related orthotics;

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

(Rule 1200-08-29-.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.

(~~21~~20) Home medical equipment provider. Any person who provides home medical equipment services.

(~~22~~21) Home medical equipment services. A service provided by any person who sells or rents home medical equipment for delivery to the consumer' place of residence in this state, regardless of the location of the home medical equipment provider.

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

(~~24~~23) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~25~~24) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

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

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

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

(~~26~~25) Legal Conservator. Any person authorized to act for the patient pursuant to any provision of T.C.A. Title 34, Chapters 5 and 11 through 13.

(~~27~~26) Legal Guardian. Any person authorized to act for the resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

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

(~~29~~28) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~30~~29) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~31~~30) Medical Record. Information that pertains to confinement or services rendered to patients, including one or more of the following:

(a) medical histories;

(b) records;

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

(c) reports;

(d) clinical notes;

(e) summaries; or

(f) orders.

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

(~~32~~31) Medical Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(~~33~~32) 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.

(~~34~~33) 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.

(~~35~~34) 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.

(~~36~~35) 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).

(~~37~~36) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~38~~37) Shall or Must. Compliance is mandatory.

(~~39~~38) 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.

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

(~~40~~39) 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.~~

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

(~~43~~40) Wheeled Mobility Device. A wheelchair or wheelchair and seated positioning system prescribed by a physician and required for use by the patient for a period of six (6) months or more. The following Medicare wheelchairs base codes are exempt: K0001, K0002, K0003, K0004, K0006, and K0007 as long as the consumer weighs less than three hundred (300) pounds.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-226, 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. Amendments filed December 23, 2009; effective March 23, 2010.*

1200-08-29-.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. 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 30th. 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.

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

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

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

(a) Isolate the area;

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

(c) Sanitize all contaminated equipment and surfaces appropriately.

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

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

~~(1) 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 1200-08-29-.11, 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,~~

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

~~within seven (7) days after the facility learns of the incident. These specific incidents include the following:~~

~~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.~~

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

~~(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.~~

~~(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.~~

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

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

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

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

(~~2~~3) Patient Records shall be maintained for each patient who receives in-home services. The patient record must contain detailed, accurate documentation that reflects all of the services or care provided, directly or by contract. The patient record shall contain at a minimum the following:

(a) Documentation of patient education and instruction;

(b) Physician orders as required;

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

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

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

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

3. Voice grievances without fear of discrimination or reprisal;

4. Confidentiality of personal information;

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

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

(~~3~~4) Patient Confidentiality. The agency shall have written policies dealing with patient information. Patient records shall contain signed release of information statements/forms when the agency bills a third-party payor or shares information with others outside the agency. Patient confidentiality polices will address, at a minimum, the following:

(a) A definition of confidential information;

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

(c) Conditions which warrant release of confidential information;

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

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

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

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

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

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

1200-08-29-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

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

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

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

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

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

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

1200-08-29-.13 REPEALED.

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

1200-08-29-.14 DISASTER PREPAREDNESS.

(1) All agencies shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information

RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-32
STANDARDS FOR END STAGE RENAL DIALYSIS CLINICS

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1200-08-32-.01 DEFINITIONS.

(1) Adult. An individual who has capacity and is at least 18 years of age.

(2) 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.

(3) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(4) Anticoagulant. A medication or medical technique to prevent or slow down coagulation and clotting.

(5) Anticoagulation. The process of inhibiting the blood clotting mechanism by the administration of certain drugs.

(6) Artificial Kidney. An apparatus which removes metabolic wastes or other poisons from the body when the natural kidneys are not functioning properly. This apparatus may be referred to as a kidney dialyzer.

(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.

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

(Rule 1200-08-32-.01, continued)

(10) Chronic Hemodialysis. Hemodialysis over a long period of time, usually to the extent of the patient's life or organ transplant.

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

(12) Competent. A patient who has capacity.

~~(13) 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.~~

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

(~~15~~14) 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.

(~~16~~15) Dialysis. A process by which substances are removed from a patient's body by diffusion and convection from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

(~~17~~16) Dialysis technician. An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician, dialysis assistant or dialysis technician.

(~~18~~17) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners or exempted from licensure by T.C.A. §63-25-104 and having at least one (1) year of experience in clinical nutrition.

(~~19~~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.

(~~20~~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.

(~~21~~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.

(~~22~~21) End-Stage Renal Disease (ESRD). That stage of renal impairment that is or appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

(Rule 1200-08-32-.01, continued)

(~~23~~22) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~24~~23) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

(~~25~~24) 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).

(~~26~~25) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~27~~26) 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 1200-08-32-.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.

(~~28~~27) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~29~~28) 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.

(~~30~~29) Home dialysis. Dialysis performed by a trained patient on him or herself or by a trained designated caregiver on the patient at the patient's home with little or no professional assistance.

(~~31~~30) Home dialysis training. A training program that teaches dialysis patients and patient caregivers to perform home dialysis.

(~~32~~31) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~33~~32) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such person, and maternity care involving labor and delivery for any period of time.

(~~34~~33) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~35~~34) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~36~~35) 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.

(Rule 1200-08-32-.01, continued)

(~~37~~36) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~38~~37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~39~~38) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~40~~39) Medical Director. A physician who: (1) Is board eligible or board certified in nephrology, internal medicine or pediatrics by a professional board, and has at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program; and worked within the field of kidney dialysis for at least 12 months in the past 5 years. However, in the areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a dialysis facility, another physician may direct the facility, subject to the approval of the Department.

(~~41~~40) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~42~~41) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written, electronic, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients.

(~~43~~42) 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.

(~~44~~43) NFPA. The National Fire Protection Association.

(~~45~~44) Nurse Manager. A Registered Nurse who is employed full time in a renal dialysis clinic, is currently licensed as such by the Tennessee Board of Nursing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has at least 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. If the Nurse Manager is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience must be in training patients in self-care.

(~~46~~45) Nurse Practitioner/Clinical Nurse Specialist. A person currently licensed as a registered nurse by the Tennessee Board of Nursing and certified by the American Academy of Nurse Practitioners, the American Nurses Credentialing Center as a nurse practitioner or holds a certification as clinical nurse specialist from the Tennessee Board of Nursing.

(~~47~~46) Nursing Personnel. Licensed nurses and certified nurse aides, who provide nursing care.

(~~48~~47) On-Duty/On-Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.

(Rule 1200-08-32-.01, continued)

(~~49~~48) On-Site. A staff person who is on the facility's premises but is only required to be on duty during an emergency.

(~~50~~49) 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; 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.

(~~51~~50) Patient Care Plan. A written document prepared by the interdisciplinary team for a patient receiving end stage renal disease services.

(~~52~~51) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~53~~52) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~54~~53) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~55~~54) Physician's Assistant. A person who is currently licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).

(~~56~~55) 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.

(~~57~~56) 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.

(~~58~~57) 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.

(~~59~~58) Referring physician. The physician who refers the patient to the renal dialysis clinic for treatment.

(~~60~~59) Renal dialysis clinic. Any institution, facility, place or building devoted to the provision of renal dialysis on an outpatient basis to persons diagnosed with end stage renal disease.

(~~61~~60) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~62~~61) Shall or Must. Compliance is mandatory.

(~~63~~62) Social Worker. A person who is licensed by the Tennessee Board of Social Worker Certification and Licensure, if applicable, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least

(Rule 1200-08-32-.01, continued)

2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program and has established a consultative relationship with a social worker who qualifies in paragraph (1) of this definition.

(~~64~~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.

(~~65~~64) 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~~65) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~67~~66) Survey. An on-site examination by the Department to determine compliance with state and federal regulations.

(~~68~~67) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(~~69~~68) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."

(69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(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~~70) Water Treatment. The process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets AAMI (Association for the Advancement of Medical Instrumentation) standards.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed December 9, 2010 to have been effective March 9, 2011 was stayed for 28 days by the Government Operations Committee; new effective date March 29, 2011.*

1200-08-32-.02 LICENSING PROCEDURES.

(Rule 1200-08-32-.10, continued)

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) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall 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 April 22, 2003; effective July 6, 2003.*

1200-08-32-.11 RECORDS AND REPORTS.

(1) The renal dialysis clinic shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(2) 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;~~

~~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;~~

(Rule 1200-08-82-.11, continued)

~~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:~~

~~1. strike by the staff at the facility;~~

~~2. external disaster impacting the facility;~~

(Rule 1200-08-82-.11, continued)

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,

(Rule 1200-08-82-.11, continued)

~~it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(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.~~

(2) The renal dialysis clinic shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The renal dialysis clinic shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ESRD or to the health and safety of its patients and personnel; and

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

(~~3~~4) The renal dialysis clinic shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(Rule 1200-08-82-.11, continued)

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and findings, if any; and,

(h) Maintenance records of all safety equipment.

(45) Copies of the records and reports listed above, with the exception of patient records, shall be maintained in a location convenient to the public and, during normal business hours. They shall be made available for inspection by any person who requests to view them. Each patient and/or person assuming any financial responsibility for a patient shall be fully informed, before or at the time of admission, of the availability of these reports.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, and 68-11-211.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-08-32-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within seven (7) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. §71-6-101 et seq;

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

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

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The renal dialysis clinic must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in all aspects of their care.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed December 15, 2005; effective February 28, 2006.*

1200-08-32-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each end stage renal dialysis clinic shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of

(Rule 1200-08-32-.13, continued)

them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(Rule 1200-08-32-.13, continued)

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-32-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

(Rule 1200-08-32-.13, continued)

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-32-.13(16)(c) thru 1200-08-32-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-32-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-32-.13(20) thru 1200-08-32-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-32-.13(20) thru 1200-08-32-.13(22) shall:

(Rule 1200-08-32-.13, continued)

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

(Rule 1200-08-32-.13, continued)

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving~~

(Rule 1200-08-32-.13, continued)

~~health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-32-.14 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies, for evacuation to areas of refuge and /or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:

(a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures; and

5. Staff functions by department and job assignment.

(b) Tornado/Severe Weather Procedures Plan shall include:

1. Staff duties by department and job assignment; and

2. Evacuation procedures.

RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-34
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING PROFESSIONAL SUPPORT SERVICES

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1200-08-34-.01 DEFINITIONS.

(1) Administrator. A person who establishes policies and procedures and is responsible for the activities of the agency and its staff. This person may be a physician, registered nurse, therapist, or a person with at least one (1) year experience in a health or disability related field. The administrator of a home care organization may serve as both a home health agency and professional support service agency administrator if both agencies are owned by the same corporation or legal entity.

(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) Agency. A home care organization providing professional support services.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

~~(6) Analysis. A process for identifying the most basic or causal factor or factors that underlie variation in performance leading to an unusual event. The analysis must contain the following analytical processes: the proximate cause of the unusual event, an analysis of systems and processes involved in the unusual event, identification of possible common causes, identification of potential improvements, the plan of correction or action plan, and measures of effectiveness.~~

(~~7~~6) Board. The Tennessee Board for Licensing Health Care Facilities.

(~~8~~7) 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 consumer to make health care decisions while having the capacity to do so. A consumer 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 consumer shall have the burden of proving lack of capacity.

(Rule 1200-08-34-.01, continued)

(~~9~~8) Clinical Note. A written and dated notation containing a consumer assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the consumer.

(~~10~~9) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(~~11~~10) Competent. A consumer who has capacity.

(~~12~~11) Comprehensive Nursing assessment. An assessment conducted by a registered nurse which consists of four parts: completion of a Physical Status Review (PSR); consumer and family history; identification of health concerns, functional abilities, activities of daily living; and, completion of a head to toe physical assessment.

(~~13~~12) Consumer. Any person with a primary diagnosis of mental retardation or developmental disability served through the Division of Mental Retardation Services or the Department of Mental Health and Developmental Disabilities in need of nursing, occupational, physical or speech therapy through a professional support service agency.

~~(14) Corrective Action Plan/Report. A report filed with the department by the agency 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.~~

(~~15~~13) Department. The Tennessee Department of Health.

(~~16~~14) 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.

(~~17~~15) 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.

(~~18~~16) 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.

(~~19~~17) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~20~~18) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~21~~19) 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).

(~~22~~20) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(Rule 1200-08-34-.01, continued)

(~~23~~21) Health Care Decision-maker. In the case of a consumer who lacks capacity, the consumer's health care decision-maker is one of the following: the consumer's health care agent as specified in an advance directive, the consumer's court-appointed guardian or conservator with health care decision-making authority, the consumer's surrogate as determined pursuant to Rule 1200-08-34-.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.

(~~24~~22) Health Care Institution. A health care institution as defined in T.C.A. §68-11-1602.

(~~25~~23) 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.

(~~26~~24) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~27~~25) Individual Support Plan (ISP). The document resulting from a process of person-centered planning. The ISP describes in detail the person, including his/her vision for his/her future, preferences, non-negotiables, and other information required to support the person in daily life. The ISP contains outcomes to be achieved with the assistance of the person's Circle of Support that relate to the person's vision for the future. The ISP is written upon a person's enrollment in Department of Mental Retardation Services and updated thereafter as changes occur in the individual's life, or at least annually.

(~~28~~26) 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.

(~~29~~27) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~30~~28) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~31~~29) Life Threatening or Serious Injury. Injury requiring the consumer to undergo significant additional diagnostic or treatment measures.

(~~32~~30) 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 consumers. The medical record shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.

(~~33~~31) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the consumer or other medical or surgical treatments to achieve the expressed goals of the informed consumer. In the case of the incompetent consumer, the consumer's representative expresses the goals of the consumer.

(~~34~~32) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~35~~33) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(Rule 1200-08-34-.01, continued)

(~~36~~34) Patient/Consumer Abuse. Patient/consumer neglect, intentional infliction of pain, injury, or mental anguish. Patient/consumer abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or consumer; 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/consumer abuse" for purposes of these rules.

(~~37~~35) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~38~~36) Personally Informing. A communication by any effective means from the consumer directly to a health care provider.

(~~39~~37) Physical Status Report (PSR). An instrument used by a registered nurse or other designated professional staff to determine level of risk and define the required health services and supports.

(~~40~~38) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~41~~39) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~42~~40) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~43~~41) Plan of Care. Health care plan resulting from the comprehensive nursing assessment and/or therapy plan identifying the need for nursing, physical, occupational, or speech therapy for consumers of professional support services. The plan shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.

(~~44~~42) 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.

(~~45~~43) Professional Support Services. Nursing, occupational, physical or speech therapy services provided to individuals with mental retardation or developmental disabilities pursuant to a contract with the state agency financially responsible for such services.

(~~46~~44) 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.

(~~47~~45) 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 consumer's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~48~~46) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~49~~47) Shall or Must. Compliance is mandatory.

(Rule 1200-08-34-.01, continued)

(~~50~~48) Site Code. An approved location from which the professional support services may be provided as deemed by the Department of Mental Retardation Services with written notice provided to the Department of Health by the professional support service agency for each site code approved for such agency.

(~~51~~49) Speech Language Pathologist. A person currently licensed as such by the Tennessee Board of Communication Disorders and Sciences or, for purposes of these rules, a Speech Language Pathologist who is currently in their Clinical Fellowship Year.

(~~52~~50) 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.

(~~53~~51) 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.

(~~54~~52) 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.

(~~55~~53) Surrogate. An individual, other than a consumer's agent or guardian, authorized to make a health care decision for the consumer.

(~~56~~54) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the consumer.

~~(57) 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.~~

(55) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(58) Unusual Event. The abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer that is not related to a natural course of the consumer's illness or underlying condition.~~

~~(59) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 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 January 24, 2003; effective April 9, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-34-.02 LICENSING PROCEDURES.

(Rule 1200-08-34-.10, continued)

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

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

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

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

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

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

(a) Isolate the area;

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

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-08-34-.11 RECORDS AND REPORTS.

(1) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Department licensure and fire safety inspections and surveys;

(b) Centers for Medicare and Medicaid Services (CMS) surveys and inspections, if any;

(c) Orders of the Commissioner or Board, if any; and

(d) Comptroller of the Treasury's audit report and finding, if any.

~~(2) Unusual events shall be reported by the agency 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 consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer.~~

(Rule 1200-08-34-.11, continued)

~~(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 consumer, not related to a natural course of the consumer'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 consumer 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 consumer;~~

~~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;~~

~~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; and~~

~~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 re-operation 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;~~

(Rule 1200-08-34-.11, continued)

~~(xiii) criminal acts;~~

~~(xiv) suicide or attempted suicide;~~

~~(xv) elopement from the agency;~~

~~(xvi) infant abduction, or infant discharged to the wrong family;~~

~~(xvii) adult abduction;~~

~~(xviii) rape;~~

~~(xix) consumer altercation;~~

~~(xx) consumer abuse, consumer neglect, or misappropriation of consumer funds;~~

~~(xxi) restraint related incidents; or~~

~~(xxii) poisoning occurring within the agency.~~

~~(b) Specific incidents that might result in a disruption of the delivery of professional support services at the agency shall also be reported to the department, on the unusual event form, within seven (7) days after the agency learns of the incident. These specific incidents include the following:~~

~~1. strike by the staff at the agency;~~

~~2. external disaster impacting the agency;~~

~~3. disruption of any service vital to the continued safe operation of the agency or to the health and safety of its consumers and personnel; and~~

~~4. fires at the agency which disrupt the provision of consumer care services or cause harm to consumers or staff, or which are reported by the agency to any entity, including but not limited to a fire department, charged with preventing fires.~~

~~(c) For professional support services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the agency 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 agency utilized an analysis in identifying the most basic or casual 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 agency will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

(Rule 1200-08-34-.11, continued)

~~(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 agency with a list of actions that the department believes are necessary to address the errors. The agency 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 agency 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 agency. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to agency records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of an agency 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 agency explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against an agency, or from taking a disciplinary action against an agency. 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 agency. 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 consumer and/or the consumer's family, as may be appropriate, shall also be notified of the event or incident by the agency.~~

~~(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 agencies to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of agencies 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~~

(Rule 1200-08-34-.11, continued)

~~(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 agency with a list of actions that the department believes are necessary to address the errors. The agency 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 agency 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 agency. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to agency records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of an agency 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 agency explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against an agency, or from taking a disciplinary action against an agency. 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 agency. 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 consumer and/or the consumer's family, as may be appropriate, shall also be notified of the event or incident by the agency.~~

~~(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 agencies to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of agencies 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~~

(Rule 1200-08-34-.11, continued)

~~with agencies to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(2) The agency providing professional support services shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The agency providing professional support services shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, and 68-11-211.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-08-34-.12 CONSUMER RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To have appropriate assessment and management of pain;

(c) To be involved in the decision making and all aspects of their care;

(d) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;

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

(f) To refuse experimental treatment and drugs. The consumer's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record; and

(g) To have their records kept confidential and private. Written consent by the consumer must be obtained prior to release of information except to persons authorized by law. If the consumer lacks capacity, written consent is required from the consumer's health

(Rule 1200-08-34-.12, continued)

care decision maker. The agency must have policies to govern access and duplication of the consumer's record.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed December 2, 2005; effective February 15, 2006.*

1200-08-34-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each professional support services agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a consumer who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual consumers. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the consumer could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the consumer could have made while having capacity.

(3) The advance directive shall be in writing, signed by the consumer, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the consumer by blood, marriage, or adoption and would not be entitled to any portion of the estate of the consumer upon the death of the consumer. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the consumer lacks capacity, and ceases to be effective upon a determination that the consumer has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a consumer lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the consumer's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the consumer's best interest. In determining the

(Rule 1200-08-34-.13, continued)

consumer's best interest, the agent shall consider the consumer's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the consumer's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A consumer having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A consumer having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a consumer who is an adult or emancipated minor if and only if:

1. the consumer has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a consumer who lacks capacity, the consumer's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the consumer is receiving health care.

(Rule 1200-08-34-.13, continued)

(d) The consumer's surrogate shall be an adult who has exhibited special care and concern for the consumer, who is familiar with the consumer's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the consumer's spouse, unless legally separated;

2. the consumer's adult child;

3. the consumer's parent;

4. the consumer's adult sibling;

5. any other adult relative of the consumer; or

6. any other adult who satisfies the requirements of 1200-08-34-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the consumer shall be eligible to serve as the consumer's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the consumer or in accordance with the consumer's best interests;

2. The proposed surrogate's regular contact with the consumer prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the consumer during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the consumer lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-34-.13(16)(c) thru 1200-08-34-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the consumer after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the consumer's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-34-.13, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the consumer's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the consumer's best interest. In determining the consumer's best interest, the surrogate shall consider the consumer's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the consumer may make all health care decisions for the consumer that the consumer could make on the consumer's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a consumer upon a decision of the surrogate only when the designated physician and a second independent physician certify in the consumer's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the consumer is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-34-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the consumer's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the consumer by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a consumer to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the consumer's individual instructions and may not revoke the consumer's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a consumer to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a consumer lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-34-.13, continued)

the consumer's current clinical record and communicate the determination to the consumer, if possible, and to any person then authorized to make health care decisions for the consumer.

(19) Except as provided in 1200-08-34-.13(20) thru 1200-08-34-.13(22), a health care provider or institution providing care to a consumer shall:

(a) comply with an individual instruction of the consumer and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the consumer; and

(b) comply with a health care decision for the consumer made by a person then authorized to make health care decisions for the consumer to the same extent as if the decision had been made by the consumer while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the consumer or to a person then authorized to make health care decisions for the consumer.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-34-.13(20) thru 1200-08-34-.13(22) shall:

(a) promptly so inform the consumer, if possible, and any person then authorized to make health care decisions for the consumer;

(b) provide continuing care to the consumer until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the consumer or person then authorized to make health care decisions for the consumer refuses assistance, immediately make all reasonable efforts to assist in the transfer of the consumer to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a consumer has the same rights as the consumer to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-34-.13, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a consumer, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a consumer in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate order may be used by a physician for a patient with whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-34-.13, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the consumer is an adult who is capable of making an informed decision, the consumer's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the consumer is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the consumer be resuscitated by the person authorized to consent on the consumer's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the consumer in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the consumer's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a consumer in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

(Rule 1200-08-34-.13, continued)
Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-34-.14 RESERVED.

RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-35
STANDARDS FOR OUTPATIENT DIAGNOSTIC CENTERS

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1200-08-35-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division approves an Outpatient Diagnostic Center's plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Adult. An individual who has capacity and is at least 18 years of age.

(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) 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.

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

(7) Cancer Treatment and Radiation Clinic. A facility in which the only procedures performed are diagnostic and therapeutic radiology, chemotherapy and related services.

(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.

(Rule 1200-08-35-.01, continued)

Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(9) Cardiac Catheterization. An invasive procedure in which a transluminal catheter is inserted into the femoral, internal jugular or antecubital vein and guided through the venous system into the heart chambers and/or coronary arteries while the patient is under conscious sedation in order to provide anatomic information on the heart chambers, coronary arteries, valves, myocardium, and the great vessels.

(10) 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 ventilators or respirators, 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.

(11) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(12) Collaborative Plan. The formal written plan between the mid-level practitioners and licensed physician.

(13) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians, mid-level practitioners or nurse midwives.

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

(15) Competent. A patient who has capacity.

(16) Computerized Tomography. A non-invasive radiological diagnostic procedure that may or may not include nuclear medical dye.

(17) Conscious Sedation. A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patient airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.

~~(18) 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 incident,~~

~~(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.~~

(~~19~~18) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(~~20~~19) Department. The Tennessee Department of Health.

(Rule 1200-08-35-.01, continued)

(~~21~~20) 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.

(~~22~~21) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical records 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.

(~~23~~22) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(~~24~~23) 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.

(~~25~~24) 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.

(~~26~~25) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(~~27~~26) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~28~~27) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~29~~28) 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).

(~~30~~29) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~31~~30) 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 1200-08-35-.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.

(~~32~~31) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~33~~32) 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.

(~~34~~33) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(Rule 1200-08-35-.01, continued)

(~~35~~34) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~36~~35) 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.

(~~37~~36) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~38~~37) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules and regulations.

(~~39~~38) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~40~~39) Lithotripsy. A technique using extracorporeal shock waves to break up stones that form in the kidney, bladder, ureters, or gallbladder while monitoring through x-ray or ultrasound.

(~~41~~40) Magnetic Resonance Imaging (MRI). A non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

(~~42~~41) Mammography. A non-invasive radiological procedure used to take pictures of the breasts in order to diagnose tumors or cysts.

(~~43~~42) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~44~~43) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~45~~44) Medical Staff. An organized body composed of individuals appointed by the Outpatient Diagnostic Center governing board. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(~~46~~45) 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.

(~~47~~46) Mid-Level Practitioner. A registered nurse licensed in Tennessee who holds a master's degree in a clinical nursing specialty, national certification through the ANCC or American Academy of Nurse Practitioners and holds a certificate of fitness to prescribe from the Tennessee Board of Nursing.

(~~48~~47) N.F.P.A. National Fire Protection Association.

(Rule 1200-08-35-.01, continued)

(~~49~~48) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(~~50~~49) Outpatient Diagnostic Center. Any facility providing outpatient diagnostic services (computerized tomography, magnetic resonance imaging, positron emission tomography, or other imaging technology developed after June 9, 2005 which provides substantially the same functionality), unless the outpatient diagnostic services are provided as the services of another licensed healthcare institution that reports such outpatient diagnostic services on its joint annual report, or the facility is otherwise excluded from this definition. Outpatient diagnostic center does not include a physician or dental practice that is conducted at a location occupied and controlled by one or more physicians or dentists licensed under Title 63, if the outpatient diagnostic services are ancillary to the specialties of the physicians' practice or are provided primarily for persons who are patients of the physicians or dentists in the practice for purposes other than outpatient diagnostic services. Outpatient diagnostic centers in existence prior to the effective date of this rule will be required to obtain licensure by the department of health and comply with relevant reporting requirements.

(~~51~~50) 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.

(~~52~~51) Patient Abuse. atient 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.

(~~53~~52) Percutaneous Transluminal Coronary Angioplasty. An invasive diagnostic procedure in which a transluminal catheter is guided through the femoral, subclavian, internal jugular or antecubital vein allowing the passage of a balloon-tipped catheter distally into the coronary artery while viewing through radiological pictures. The balloon is aligned within the stenosis and inflated to dilate the vessel with or without the use of anticoagulants to reduce the incidence of thrombosis at the site of balloon dilation and calcium blockers or nitrates to reduce coronary spasm. Conscious sedation and local anesthesia at catheter insertion site are utilized during the procedure.

(~~54~~53) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~55~~54) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~56~~55) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~57~~56) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. §63-19-107(2)(A).

(~~58~~57) Positron Emission Tomography (PET Scan). A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography.

(Rule 1200-08-35-.01, continued)

(~~59~~58) 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.

(~~60~~59) 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.

(~~61~~60) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.

(~~62~~61) 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.

(~~63~~62) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.

(~~64~~63) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.

(~~65~~64) Shall or Must. Compliance is mandatory.

(~~66~~65) 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.

(~~67~~66) Stereotactic Procedure. An invasive technique utilized for precisely directing the tip of a delicate needle or beam of radiation in three planes using coordinates provided by medical imaging such as x-ray or CT scan in order to reach a specific location in the body, eg. tumor.

(~~68~~67) 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.

(~~69~~68) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~70~~69) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(~~71~~70) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(71) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(72) 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 shall serve as a Universal DNR according to these rules.~~

(Rule 1200-08-35-.10, continued)

disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks 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 a 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) The 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 subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious wastes 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, be constructed of easily cleanable material and be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.11 RECORDS AND REPORTS.

(1) The Joint Annual Report of Outpatient Diagnostic Centers shall be filed with the department. The forms are furnished and mailed to each Outpatient Diagnostic Center by the department each year and the forms must be completed and returned to the department as required.

(2) The facility shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(Rule 1200-08-35-.11, continued)

(3) The Outpatient Diagnostic Center shall report to the department each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of an Outpatient Diagnostic Center's license.

~~(4) 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;~~

~~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;~~

(Rule 1200-08-35-.11, continued)

~~(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 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:~~

~~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~~

(Rule 1200-08-35-.11, continued)

~~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.~~

~~(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.~~

(Rule 1200-08-35-.11, continued)

~~(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) The outpatient diagnostic center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(5) The outpatient diagnostic center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the outpatient diagnostic center or to the health and safety of its patients and personnel; and

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

(~~5~~6) Legible copies of the following records and reports shall be retained in the Outpatient Diagnostic Center, shall be maintained in a single file, and shall be made available for inspection during normal business hours to any patient who requests to view them for thirty-six (36) months following their issuance:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(f) Federal Center for Medicare and Medicaid Services surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and findings, if any;

(i) Maintenance records of all safety equipment; and

(j) Radiological inspection reports.

(Rule 1200-08-35-.11, continued)

(6) Copies of patient's medical records shall be maintained for at least ten (10) years.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, and 68-11-216.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.12 PATIENT RIGHTS.

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

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

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

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

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The outpatient diagnostic center must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in the decision making of all aspects of their care.

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

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each outpatient diagnostic center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the

(Rule 1200-08-35-.13, continued)

agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility may use any advance directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(Rule 1200-08-35-.13, continued)

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-35-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

(Rule 1200-08-35-.13, continued)

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-35-.13(16)(c) thru 1200-08-35-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-35-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

(Rule 1200-08-35-.13, continued)

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-35-.13(20) thru 1200-08-35-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(Rule 1200-08-35-.13, continued)

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-35-.13(20) thru 1200-08-35-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

(Rule 1200-08-35-.13, continued)

~~(a) A universal do not resuscitate order (DNR) may be issued by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

(Rule 1200-08-35-.13, continued)

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1803, 68-11-1804, 68-11-1806 through 68-11-1810, 68-11-1813, and 68-11-1814.* ***Administrative History****: Original rule filed October 26, 2005; effective January 9, 2006.*

1200-08-35-.14 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans and the specific emergency numbers related to that type of disaster shall be readily available at all times. Each of the following plans shall be exercised annually:

(a) Fire Safety Procedures Plan shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures;

5. Staff functions.

(b) Tornado/Severe Weather Procedures Plan shall include:

RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH CARE FACILITIES

CHAPTER 1200-24-5
REVIEW OF HEALTH CARE FACILITY CONSTRUCTION PLANS AND SPECIFICATIONS

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1200-24-5-.01 DEFINITIONS.

(1) Board. The Board for Licensing Health Care Facilities.

(2) Construction. The erection of a new building, an addition to an existing building, a change of occupancy, an alteration that reconfigures the exit arrangement, fire-resistive assemblies, or type of construction, or involves the installation of fire suppression or detection systems or fuel fired equipment. The term construction shall not be construed to include excavation or site preparation.

(3) Department. The Department of Health.

(4) Division. The Division of Health Care Facilities.

(5) Health care facility. Includes any hospital, recuperation center, nursing home, home for the aged, alcohol and drug prevention and/or treatment facility, birthing center, ambulatory surgical treatment center, or residential HIV supportive living facility required to be licensed in accordance with Tennessee Code Annotated § 68-11-201.

(6) N.F.P.A. The National Fire Protection Association.

(7) Occupancy type. Business occupancy, residential occupancy, health care institution occupancy as defined in the 2000 edition of the Life Safety Code (NFPA 101-2000).

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed February 18, 2003; effective May 4, 2003.*

1200-24-5-.02 SUBMISSION OF PLANS.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall commence construction of any health care facility until plans and specification have been submitted to and approved in writing by the Department.

(2) Any construction may be undertaken prior to approval of final plans and specification if:

(a) The phased plans adequately describing the nature and scope of the project have been submitted to the Department; and

(b) Complete plans and specification for that phase of construction to be undertaken have been submitted to the Department, and such plans and specifications have been approved in writing.

(Rule 1200-24-5-.02, continued)

(3) The Department has failed to transmit a written evaluation of such plans and specifications within thirty (30) working days after receipt thereof.

(4) In the event that submitted materials do not appear to satisfactorily comply with the existing codes, the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(5) Resubmission of the complete plans and specifications for any proposed project which is identical in structure and interior arrangement to one already reviewed and approved in accordance with this chapter is required, however, the Department may reduce the review fee for resubmission.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

1200-24-5-.03 FEES.

~~(1) The fee schedule for review of plans and specifications for construction shall be as specified in the following table:~~

~~Total Construction Cost:~~	~~Fee:~~
~~$ 1.00 to $ 50,000~~	~~$260.~~
~~$ 50,001. to $ 100,000.~~	~~$260. for the first $50,000., plus $3.00 for each additional thousand or fraction thereof, to and including $100,000.~~
~~$ 100,001. to $ 500,000.~~	~~$410. for the first $100,000., plus $2.00 for each additional thousand or fraction thereof, to and including $500,000.~~
~~$ 500,001. and up~~	~~$1,210. for the first $500,000., plus $1.50 for each additional thousand or fraction thereof, with a maximum of $20,000.~~

(1) The fee schedule for review of plans and specifications for construction shall be specified in the following table:

Total Project Construction Cost	Fee
$0.00 to $1,000,000.00	$2.50 per thousand or fraction thereof ($250.00 minimum)
$1,000,000.01 or more	$2,500.00 for the first $1,000,000.00 plus $2.00 for each additional thousand or fraction thereof.

(2) The fee shall be payable and due at the time of initial submission of plans and specifications.

(a) The fee for obtaining a letter stating that plans are not required to be reviewed (a "no review letter") shall be one hundred dollars ($100.00).

(Rule 1200-24-5-.03, continued)

(b) The fee shall be applied to the fee for review of plans and specifications for construction if it is determined that plans are required to be reviewed.

(3) The fee for review of plans and specifications for minor renovations, locking hardware, hood and duct suppression shall be three hundred dollars ($300.00).

(4) The fee for review of plans and specifications for Homes for the Aged (RHAs) licensed for six (6) beds or fewer shall be three hundred dollars ($300.00).

(~~3~~5) Filing fees are non-refundable and must be received by the Department prior to beginning the required thirty-day review cycle.

(~~4~~6) If plans and specifications must be resubmitted due to the expiration of the twelve (12) month approval period as specified under Rule 1200-24-5-.04, a new fee established under these rules shall be imposed. Extensions to the approval period may be granted upon submission of written request to the Department.

(~~5~~7) The Department may require appropriate documentation of cost, such as, contractors' bids or invoices if:

(a) In its opinion, the construction cost of a project has been underestimated in the certification submitted pursuant to these rules; or

(b) The scope of a project is substantially revised after initial plans submission.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 68-11-804.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed February 28, 2002; effective May 14, 2002.*

1200-24-5-.04 APPROVAL OF PLANS.

(1) Plans and specifications submitted pursuant to these rules shall be approved only if the proposed construction would be in compliance with the minimum standards of fire prevention, fire protection, and building construction safety in effect at the time of initial submission.

(2) No final approval of plans and specifications shall be valid unless the construction represented by such plans and specifications has substantially progressed within twelve (12) months after the effective date of any adopted revisions of the building or codes standards in effect at the time of initial submission.

(3) A copy of the approved plans and specifications shall be retained on the job site through completion of the project and final inspection.

(4) Construction shall proceed in accordance with the plans and specifications as approved hereunder. If construction is completed in accordance with the approved plans and specifications, the building represented by such plans and specifications shall be exempt from subsequently adopted standards of fire prevention, fire protection, and building construction safety, unless the non-conformity of the building to such standards poses a serious life safety hazard.

(5) No approval of, or failure to review, plans and specifications by the Department shall relieve the owner, developer, designing architect or engineer of their respective responsibilities for compliance

(Rule 1200-24-5-.03, continued)

with applicable laws, rules or codes respecting fire prevention, fire protection, and building construction safety.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

1200-24-5-.05 INSPECTION OF CONSTRUCTION.

(1) When the Department inspects any construction pursuant to these rules, the inspector shall determine only whether the construction conforms to the approved plans and specification; except, however, that if such plans and specifications are not specific with respect to any applicable standard, the inspection shall be made to that standard.

(2) If upon final inspection or re-inspection of the completed project, the Department's inspector finds that only minor items remain to be completed or corrected which do not significantly affect the health or safety of the occupants, the inspector shall recommend to the Department permission to occupy, pending completion or correction of such items.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*