

**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) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.
- (19) Department. The Tennessee Department of Health.
- (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.
- (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.
- (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.
- (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.
- (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.
- (25) 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) 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) 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) 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) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.
- (30) 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) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.
- (32) 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) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.
- (34) 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) 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) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.
- (37) Individual instruction. An individual's direction concerning a health care decision for the individual.
- (38) 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) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (40) 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) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (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.

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

- (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.
- (44) 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) 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) 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) N.F.P.A. National Fire Protection Association.
- (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.
- (49) 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) 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) PALS. Pediatric Advance Life Support.
- (52) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
- (53) Personally Informing. A communication by any effective means from the patient directly to a health care provider.
- (54) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.
- (55) 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) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.
- (57) 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) 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) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.
- (60) 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) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.
- (62) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.
- (63) Shall or Must. Compliance is mandatory.
- (64) 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) 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) 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) Surgical Technologist. A person who currently holds a national certification by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or has completed a program for surgical technologists accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or has completed an appropriate training program for surgical technologists in the armed forces; or has successfully completed the LCC-ST certifying exam; or provides sufficient evidence that prior to July 1, 2006, the person began training or was at any time employed as a surgical technologist for not less than eighteen (18) months in a hospital, medical office, surgery center or school.
- (68) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (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.

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

- (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 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.
- (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, 68-11-216, 68-11-224, 68-11-1802, 68-57-101, and 68-57-102. **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.

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.
 - (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 ASTC until a license has been issued. Applicants shall not hold themselves out to the public as being an ASTC until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by Tennessee Code Annotated § 68-11-206(l), 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 facility.

(Rule 1200-08-10-.02, continued)

- (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 ambulatory surgical treatment center 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) Each ASTC, when issued a license, shall be classified according to the type of services rendered or category of patients served. The ASTC shall confine its services to those described in its license and shall advertise only the services which it is licensed to perform. The classification shall be listed on the license.
- (4) A proposed change of ownership 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 purposes of licensing, the licensee of an ASTC has the ultimate responsibility for the operation of the facility, 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 ASTC operations is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operation;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 6. The consolidation of a corporate facility owner with one or more corporations; or,
 - 7. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;

(Rule 1200-08-10-.02, continued)

2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner.
- (5) Renewal.
- (a) In order to renew a license, each ambulatory surgical treatment center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
 - (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.
 - (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 1. a completed application for licensure;
 2. the license fee provided in rule 1200-08-10-.02(2)(b); and
 3. any other information required by the Health Services and Development Agency.
 - (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed February 26, 1985; effective March 28, 1985. 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 January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009.

1200-08-10-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
 - (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the ASTC;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the ASTC; and
 - (e) Failure to renew license.
- (2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;
 - (c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,
 - (d) Any prior violations by the facility of statutes, regulations or orders of the board.
- (3) When an ambulatory surgical treatment center is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a policy of correction indicating the following:
 - (a) How the deficiency will be corrected;
 - (b) The date upon which each deficiency will be corrected;
 - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
 - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.
- (4) 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 ambulatory surgical treatment center's license to possible disciplinary action.
- (5) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. § 4-5-101 et seq.
- (6) **Reconsideration and Stays.** The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.

(Rule 1200-08-10-.03, continued)

Authority: T.C.A. §§4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-208, 68-11-209, and 68-11-216. **Administrative History:** Original rule 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 March 1, 2007; effective May 15, 2007.

1200-08-10-.04 ADMINISTRATION.

- (1) The ASTC must have an effective governing body legally responsible for the conduct of the ASTC. If an ASTC does not have an organized governing body, the persons legally responsible for the conduct of the ASTC must carry out the functions specified in this chapter.
- (2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the ASTC. The chief executive officer or administrator shall designate an individual to act for him or her in his or her absence, in order to provide the ASTC with administrative direction at all times.
- (3) The governing body, whether it be that of the center alone or that of a parent organization, shall establish effective mechanisms to ensure the accountability of the center's medical staff and other professional personnel.
- (4) The governing body shall assure that the ASTC has the financial resources to provide the services essential to the operation of the facility.
- (5) Staffing shall be adequate to provide the services essential to the operation of the ASTC.
- (6) The ambulatory surgical treatment center shall ensure a framework for addressing issues related to care at the end of life.
- (7) The ambulatory surgical treatment center shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.
- (8) The ASTC shall perform only those surgical procedures which can be safely and effectively carried out on an outpatient basis.
- (9) Each ASTC shall have at all times a designated Medical Director who shall be a licensed physician or dentist who shall be responsible for the direction and coordination of medical programs.
- (10) Staff education programs and training sessions shall include life safety, medical equipment, utility systems, infection control and hazardous waste practices. At least two (2) on duty members of the facility shall be trained in emergency resuscitation.
- (11) When licensure is applicable for a particular job, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.
- (12) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. An ASTC which violates a required policy also violates the rule and regulation establishing the requirement.

(Rule 1200-08-10-.04, continued)

- (13) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (14) No ASTC shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the department, the Adult Protective Services, or the Comptroller of the State Treasury. An ASTC shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.
- (15) When services such as dietary, laundry or therapy services are purchased from others, the governing body shall be responsible to assure the supplier(s) meet the same local and state standards the facility would have to meet if it were providing those services itself using its own staff.
- (16) The governing body shall provide for the appointment, reappointment or dismissal of members of the medical, dental, and other health professions and provide for the granting of clinical privileges.
- (17) The governing body shall ensure that there is a written facility agreement with one or more acute care general hospitals licensed by the state, which will admit any patient referral who requires continuing care.
- (18) Each ASTC shall specify the classification of services to be provided in the facility and list authorized surgical procedures.
- (19) Where the physician-owner-operator serves as the governing body, the articles of incorporation or other written organizational plan shall describe the manner in which the owner-operator executes the governing body responsibility.
- (20) Infection Control.
 - (a) The ASTC must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.
 - (b) The physical environment of the ambulatory surgical treatment center shall be maintained in a safe, clean and sanitary manner.
 1. Any condition on the ambulatory surgical treatment center 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 ambulatory surgical treatment center except for specially trained animals for the handicapped and except as addressed by ambulatory surgical treatment center policy for pet therapy programs. The ambulatory surgical treatment center 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 ambulatory surgical treatment center performed by medically trained personnel.

(Rule 1200-08-10-.04, continued)

3. A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
 4. Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.
 5. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
 6. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.
- (c) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee shall include the establishment of:
1. Written infection control policies;
 2. Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;
 3. Written procedures governing the use of aseptic techniques and procedures in all areas of the facility, including adoption of a standardized central venous catheter insertion process which shall contain these key components:
 - (i) Hand hygiene (as defined in 1200-08-10-.04(20)(g));
 - (ii) Maximal barrier precautions to include the use of sterile gowns, gloves, mask and hat, and large drape on patient;
 - (iii) Chlorhexidine skin antisepsis;
 - (iv) Optimal site selection;
 - (v) Daily review of line necessity; and
 - (vi) Development and utilization of a procedure checklist;
 4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 5. A log of incidents related to infectious and communicable diseases;
 6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;

(Rule 1200-08-10-.04, continued)

7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and,
 8. Continuing education provided for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.
- (d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.
- (e) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
- (f) The facility shall have an annual influenza vaccination program which shall include at least:
1. The offer of influenza vaccination to all staff and independent practitioners or accept documented evidence of vaccination from another vaccine source or facility;
 2. A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;
 3. Education of all direct care personnel about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 5. The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.
- (g) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:
1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;

(Rule 1200-08-10-.04, continued)

2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;
 3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and
 4. Health care worker education programs which may include:
 - (i) Types of patient care activities that can result in hand contamination;
 - (ii) Advantages and disadvantages of various methods used to clean hands;
 - (iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and
 - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (h) All ASTC's shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
- (21) Performance Improvement. The ASTC shall have a planned, systematic, organization-wide approach to process design and redesign, performance measurement, assessment and improvement which is approved by the designated medical staff committee of the facility, the owner and/or the governing body. This plan shall address and/or include, but is not limited to:
- (a) Infection control, including post-operative surveillance;
 - (b) Complications arising after the patient was admitted;
 - (c) Documentation of periodic review of the data collected and follow-up actions;
 - (d) A system which identifies appropriate plans of action to correct identified quality deficiencies;
 - (e) Documentation that the above policies are being followed and that appropriate action is taken whenever indicated.
 - (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;

(Rule 1200-08-10-.04, continued)

- (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.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 71-6-121. **Administrative History:** Original rule filed 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 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.

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.
- (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.

(Rule 1200-08-10-.05, continued)

- (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.

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.

(Rule 1200-08-10-.06, continued)

- (f) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as “scrub nurses” under the supervision of a registered nurse.
- (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
 - 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 July 1, 2006, the person began training to be a surgical technologist, or was at any time employed as a surgical technologist for not less than eighteen (18) months in a hospital, medical office, surgery center, or school.
- (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

(Rule 1200-08-10-.06, continued)

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
- (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 (phenytoin)
 - 8. dopamine
 - 9. heparin
 - 10. inderal (proprandolol)
 - 11. isuprel
 - 12. lanoxin (digoxin)
 - 13. lasix (furosemide)
 - 14. xylocaine (lidocaine)
 - 15. magnesium sulfate 50%

(Rule 1200-08-10-.06, continued)

16. narcan (naloxone)
 17. pronestyl (procainamide)
 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.
- (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.

(Rule 1200-08-10-.06, continued)

- (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;
 - (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.

(Rule 1200-08-10-.06, continued)

- (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 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.

(Rule 1200-08-10-.06, continued)

- (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.
- (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.

(Rule 1200-08-10-.06, continued)

- (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;
 - 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. **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

(Rule 1200-08-10-.06, continued)

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.

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 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 (if applicable), 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.
- (6) Review of plans and specifications shall be acknowledged in writing with copies sent to the architect and the owner, manager or other executive of the institution. The distribution of such review may be modified at the discretion of the department.
- (7) All construction shall be executed in accordance with the approved plans and specifications.
- (8) All new construction and renovations to ambulatory surgical treatment centers, other than minor alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in ambulatory surgical treatment centers, including the submission of phased construction plans and the final drawings and the specifications to each.

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

- (9) In the event submitted materials do not appear to satisfactorily comply with 1200-08-10-.08 (4) 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.
- (10) Notice of satisfactory review from the department constitutes compliance with this requirement if construction begins within one hundred eighty (180) days of the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.
- (11) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes.
- (12) Prior to final inspection, a CD Rom disc, in TIF or DMG format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.
- (13) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot ($1/8" = 1'$), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. These plans shall be prepared by an architect or engineer licensed to practice in the State of Tennessee. The plans shall contain a certificate signed by the architect or engineer that to the best of his or her knowledge or belief the plans conform to all applicable codes.
 - (a) Two (2) sets of plans shall be forwarded to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.
 - (b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.
- (14) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies should be bound in an 8½ x 11 inch folder.
- (15) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical, Electrical and Sprinkler.
- (16) Architectural drawings shall include:
 - (a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;
 - (b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

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

- (c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units. All fire and smoke walls must be identified;
 - (d) The elevation of each facade;
 - (e) The typical sections throughout the building;
 - (f) The schedule of finishes;
 - (g) The schedule of doors and windows;
 - (h) Roof plans;
 - (i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel must be indicated for elevators; and
 - (j) Code analysis.
- (17) Structural drawings shall include:
- (a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members;
 - (b) Schedules of beams, girders and columns; and
 - (c) Design live load values for wind, roof, floor, stairs, guard, handrails, and seismic.
- (18) Mechanical drawings shall include:
- (a) Specifications which show the complete heating, ventilating, fire protection, medical gas systems and air conditioning systems;
 - (b) Water supply, sewerage and HVAC piping systems;
 - (c) Pressure relationships shall be shown on all floor plans;
 - (d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;
 - (e) Water supply, sewage and drainage with all lines, risers, catch basins, manholes and cleanouts clearly indicated as to location, size, capacities, etc., and location and dimensions of septic tank and disposal field; and,
 - (f) Color coding to show clearly supply, return and exhaust systems.
- (19) Electrical drawings shall include:
- (a) A certification that all electrical work and equipment is in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;
 - (b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building;

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

- (c) The electrical system shall comply with applicable codes, and shall include:
 - 1. The fire alarm system; and
 - 2. The emergency power system including automatic services as defined by the codes.
 - (d) Color coding to show all items on emergency power.
- (20) Sprinkler drawings shall include:
- (a) Shop drawings, hydraulic calculations, and manufacturer cut sheets;
 - (b) Site plan showing elevation of fire hydrant to building, test hydrant, and flow data (Data from within a 12 month period); and
 - (c) Show "Point of Service" where water is used exclusively for fire protection purposes.
- (21) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.
- (a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.
 - (b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.
 - (c) Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at shower, bathing and hand washing facilities shall be between 105°F and 115°F.
- (22) The following alarms are required and shall be monitored twenty-four (24) hours per day:
- (a) Fire alarms; and
 - (b) Generators (if applicable)
- (23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.
- (24) With the submission of plans the facility shall specify the evacuation capabilities of the patients as defined in the National Fire Protection Code (NFPA). This declaration will determine the design and construction requirements of the facility.
- (25) Each ambulatory surgical treatment center shall ensure that an emergency keyed lock box is installed next to each bank of functioning elevators located on the main level. Such lock

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

boxes shall be permanently mounted seventy-two inches (72") from the floor to the center of the box, be operable by a universal key no matter where such box is located, and shall contain only fire service keys and drop keys to the appropriate elevators.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216 and 68-11-261. **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 4, 2000; effective June 4, 2000. Amendment filed February 18, 2003; effective May 4, 2003. Amendment filed June 16, 2003; effective August 30, 2003. Repeal and new rule filed September 9, 2005; effective November 23, 2005. Amendment filed February 23, 2007; effective May 9, 2007.

1200-08-10-.09 LIFE SAFETY.

- (1) Any ambulatory surgical treatment center which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.
- (2) The ambulatory surgical treatment center shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the department within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.

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. Repeal and new rule filed September 9, 2005; effective November 23, 2005.

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

- (1) Each ambulatory surgical treatment center must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes, these policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
 - (a) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals";
 - (b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;

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

- (c) Waste human blood and blood products such as serum, plasma, and other blood components;
 - (d) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;
 - (e) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;
 - (f) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;
 - (g) Other waste determined to be infectious by the facility in its written policy.
- (3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.
- (4) 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) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;
 - (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;
 - (d) Opaque packaging must be used for pathological waste.
- (5) 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.
- (a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal;
 - (b) Plastic bags of infectious waste must be transported by hand.
- (6) 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.

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

- (a) 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.
 - (b) Pathological waste must be promptly treated, disposed of, or placed into refrigerated storage.
- (7) In the event of spills, ruptured packaging, 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 from the public and all except essential personnel;
 - (b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of paragraph (6) of this section; and
 - (c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done.
 - (d) Complete incident report and maintain copy on file.
- (8) Except as provided otherwise in this section a facility must treat or dispose of infectious waste by one or more of the methods specified in this part.
- (a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious wastes treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or 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

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

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.
- (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;

(Rule 1200-08-10-.11, continued)

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;
 - (xvi) infant abduction, or infant discharged to the wrong family;
 - (xvii) adult abduction;

(Rule 1200-08-10-.11, continued)

- (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 agree on an appropriate corrective action plan, then the final

(Rule 1200-08-10-.11, continued)

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.
- (5) 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;

(Rule 1200-08-10-.11, continued)

- (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, 68-1-1004, 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.

(Rule 1200-08-10-.12, continued)

- (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.
- (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 1200-08-10-.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 1200-08-10-.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 1200-08-10-.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.

(Rule 1200-08-10-.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 1200-08-10-.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:

(Rule 1200-08-10-.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 1200-08-10-.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;

(Rule 1200-08-10-.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.
 - (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 1200-08-10-.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.
- (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.

- (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:
 - 1. Staff duties;
 - 2. Evacuation procedures.

(Rule 1200-08-10-.14, continued)

- (c) Flood Procedure Plan, if applicable:
 - 1. Staff duties;
 - 2. Evacuation procedures;
 - 3. Safety procedures following the flood.
- (d) Earthquake Disaster Procedures Plan:
 - 1. Staff duties;
 - 2. Evacuation procedures;
 - 3. Safety procedures;
 - 4. Emergency services.
- (2) All facilities shall participate in the Tennessee Emergency Management Agency local/county emergency plan on an annual basis. Participation includes filling out and submitting a questionnaire on a form to be provided by the Tennessee Emergency Management Agency. Documentation of participation must be maintained and shall be made available to survey staff as proof of participation.
- (3) The emergency power system shall:
 - (a) Use either propane, gasoline or diesel fuel. The generator shall be designed to meet the facility's HVAC and essential needs and shall have a minimum of twenty-four (24) hours of fuel designed to operate at its rated load. The fuel quantity shall be based on its expected or known connected load consumption during power interruptions.
 - (b) Automatically transfer within ten (10) seconds in ASTC's conducting invasive surgical procedures.
 - (c) Be inspected monthly and exercised at the actual load and operating temperature conditions and not on dual power for at least thirty (30) minutes each month, including automatic and manual transfer of equipment. A log shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years. The facility shall have trained staff familiar with the generator's operation.
 - (d) Emergency generators are not required if the facility does not utilize anesthesia that renders the patient incapable of self preservation. However, the facility shall have an emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.
- (4) Emergency electrical power 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.)
- (5) In the event of natural disaster or electrical power failure, no new surgical procedures shall be begun, and surgical procedures in progress shall be brought to conclusion as soon as possible.

(Rule 1200-08-10-.14, continued)

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 November 22, 1996; effective August 27, 1997. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.

1200-08-10-.15 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED			
<p style="text-align: center;">Physician Orders for Scope of Treatment (POST)</p> <p>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, <u>first</u> follow these orders, <u>then</u> contact physician.</p>	<p>Patient's Last Name</p> <hr/> <p>First Name/Middle Initial</p> <hr/> <p>Date of Birth</p> <hr/>		
<p>Section A</p> <p>Check One Box Only</p>	<p>CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse <u>and/or</u> is not breathing.</p> <p><input type="checkbox"/> Resuscitate (CPR) <input type="checkbox"/> Do Not Attempt Resuscitate (DNR/no CPR)</p> <p>When not in cardiopulmonary arrest, follow orders in B, C, and D.</p>		
<p>Section B</p> <p>Check One Box Only</p>	<p>MEDICAL INTERVENTIONS. Patient has pulse <u>and/or</u> is breathing.</p> <p><input type="checkbox"/> 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 <u>only</u> if comfort needs cannot be met in current location.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> Full Treatment. Includes care above. Use intubation, advanced airway interventions mechanical ventilation, and cardioversion as indicated. Transfer to hospital if indicated. Include intensive care.</p> <p>Other Instructions: _____</p>		
<p>Section C</p> <p>Check One Box Only</p>	<p>ANTIBIOTICS – Treatment for new medical conditions:</p> <p><input type="checkbox"/> No Antibiotics</p> <p><input type="checkbox"/> Antibiotics</p> <p>Other Instructions: _____</p>		
<p>Section D</p> <p>Check One Box Only in Each Column</p>	<p>MEDICALLY ADMINISTERED FLUIDS AND NUTRITION. Oral fluids and nutrition must be offered if medically feasible.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> No IV fluids (provide other measures to assure comfort) <input type="checkbox"/> IV fluids for a defined trial period <input type="checkbox"/> IV fluids long-term if indicated </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> No feeding tube <input type="checkbox"/> Feeding tube for a defined trial period <input type="checkbox"/> Feeding tube long-term </td> </tr> </table> <p>Other Instructions: _____</p>	<input type="checkbox"/> No IV fluids (provide other measures to assure comfort) <input type="checkbox"/> IV fluids for a defined trial period <input type="checkbox"/> IV fluids long-term if indicated	<input type="checkbox"/> No feeding tube <input type="checkbox"/> Feeding tube for a defined trial period <input type="checkbox"/> Feeding tube long-term
<input type="checkbox"/> No IV fluids (provide other measures to assure comfort) <input type="checkbox"/> IV fluids for a defined trial period <input type="checkbox"/> IV fluids long-term if indicated	<input type="checkbox"/> No feeding tube <input type="checkbox"/> Feeding tube for a defined trial period <input type="checkbox"/> Feeding tube long-term		
<p>Section E</p>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> Discussed with: <input type="checkbox"/> Patient/Resident <input type="checkbox"/> Health care agent </td> <td style="width: 50%; vertical-align: top;"> The Basis for These Orders Is: (Must be completed) <input type="checkbox"/> Patient's preferences <input type="checkbox"/> Patient's best interest (patient lacks capacity or preferences unknown) </td> </tr> </table>	Discussed with: <input type="checkbox"/> Patient/Resident <input type="checkbox"/> Health care agent	The Basis for These Orders Is: (Must be completed) <input type="checkbox"/> Patient's preferences <input type="checkbox"/> Patient's best interest (patient lacks capacity or preferences unknown)
Discussed with: <input type="checkbox"/> Patient/Resident <input type="checkbox"/> Health care agent	The Basis for These Orders Is: (Must be completed) <input type="checkbox"/> Patient's preferences <input type="checkbox"/> Patient's best interest (patient lacks capacity or preferences unknown)		

(Rule 1200-08-10-.15 continued)

Must be Completed	<input type="checkbox"/> Court-appointed guardian <input type="checkbox"/> Health care surrogate <input type="checkbox"/> Parent of minor <input type="checkbox"/> Other: _____ (Specify)		<input type="checkbox"/> Medical indications <input type="checkbox"/> (Other) _____	
	Physician Name (Print)		Physician Phone Number	
	Physician Signature (Mandatory)		Date	
Office Use Only				
COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED				

HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY			
Signature of Patient, Parent of Minor, or Guardian/Health Care Representative			
Significant thought has been given to life-sustaining treatment. Preferences have been expressed to a physician and/or health care professional(s). This document reflects those treatment preferences.			
(If signed by surrogate, preferences expressed must reflect patient's wishes as best understood by surrogate.)			
Signature	Name (print)	Relationship (write "self" if patient)	
Contact Information			
Surrogate	Relationship	Phone Number	
Health Care Professional Preparing Form	Preparer Title	Phone Number	Date Prepared
Directions for Health Care Professionals			
<u>Completing POST</u>			
Must be completed by a health care professional based on patient preferences, patient best interest, and medical indications.			
POST must be signed by a physician to be valid. Verbal orders are acceptable with follow-up signature by physician in accordance with facility/community policy.			
Photocopies/faxes of signed POST forms are legal and valid.			
<u>Using POST</u>			
Any incomplete section of POST implies full treatment for that section.			
No defibrillator (including AEDs) should be used on a person who has chosen "Do Not Attempt Resuscitation".			
Oral fluids and nutrition <u>must</u> always be <u>offered</u> if medically feasible.			
When comfort cannot be achieved in the current setting, the person, including someone with "Comfort Measures Only", should be transferred to a setting able to provide comfort (e.g., treatment of a hip fracture).			
IV medication to enhance comfort may be appropriate for a person who has chosen "Comfort Measures Only".			
Treatment of dehydration is a measure which prolongs life. A person who desires IV fluids should indicate "Limited Interventions" or "Full Treatment".			
A person with capacity, or the surrogate of a person without capacity, can request alternative treatment.			
<u>Reviewing POST</u>			
This POST should be reviewed if:			

(Rule 1200-08-10-.15 continued)

- (1) The patient is transferred from one care setting or care level to another, or
- (2) There is a substantial change in the patient's health status, or
- (3) The patient's treatment preferences change.

Draw line through sections A through E and write "VOID" in large letters if POST is replaced or becomes invalid.

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED

(2) Advance Care Plan Form

ADVANCE CARE PLAN

Instructions: Competent adults and emancipated minors may give advance instructions using this form or any form of their own choosing. To be legally binding, the Advance Care Plan must be signed and either witnessed or notarized.

I, _____, hereby give these advance instructions on how I want to be treated by my doctors and other health care providers when I can no longer make those treatment decisions myself.

Agent: I want the following person to make health care decisions for me:

Name: _____ Phone #: _____ Relation: _____

Address: _____

Alternate Agent: If the person named above is unable or unwilling to make health care decisions for me, I appoint as alternate:

Name: _____ Phone #: _____ Relation: _____

Address: _____

Quality of Life:

I want my doctors to help me maintain an acceptable quality of life including adequate pain management. A quality of life that is unacceptable to me means when I have any of the following conditions (you can check as many of these items as you want):

- Permanent Unconscious Condition: I become totally unaware of people or surroundings with little chance of ever waking up from the coma.
- Permanent Confusion: I become unable to remember, understand or make decisions. I do not recognize loved ones or cannot have a clear conversation with them.
- Dependent in all Activities of Daily Living: I am no longer able to talk clearly or move by myself. I depend on others for feeding, bathing, dressing and walking. Rehabilitation or any other restorative treatment will not help.
- End-Stage Illnesses: I have an illness that has reached its final stages in spite of full treatment. Examples: Widespread cancer that does not respond anymore to treatment; chronic and/or damaged heart and lungs, where oxygen needed most of the time and activities are limited due to the feeling of suffocation.

Treatment:

If my quality of life becomes unacceptable to me and my condition is irreversible (that is, it will not improve), I direct that medically appropriate treatment be provided as follows. Checking "yes" means I WANT the treatment. Checking "no" means I DO NOT want the treatment.

(Rule 1200-08-10-.15 continued)

<input type="checkbox"/>	<input type="checkbox"/>	CPR (Cardiopulmonary Resuscitation): To make the heart beat again and restore breathing after it has stopped. Usually this involves electric shock, chest compressions, and breathing assistance.
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Life Support/Other Artificial Support: Continuous use of breathing machine, IV fluids, medications, and other equipment that helps the lungs, heart, kidneys and other organs to continue to work.
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Treatment of New Conditions: Use of surgery, blood transfusions, or antibiotics that will deal with a new condition but will not help the main illness.
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Tube feeding/IV fluids: Use of tubes to deliver food and water to patient's stomach or use of IV fluids into a vein which would include artificially delivered nutrition and hydration.
Yes	No	

Other instructions, such as burial arrangements, hospice care, etc.: _____

(Attach additional pages if necessary)

Organ donation (optional): Upon my death, I wish to make the following anatomical gift (please mark one):

Any organ/tissue My entire body Only the following organs/tissues: _____

SIGNATURE

Your signature should either be witnessed by two competent adults or notarized. If witnessed, neither witness should be the person you appointed as your agent, and at least one of the witnesses should be someone who is not related to you or entitled to any part of your estate.

Signature: _____ DATE: _____
(Patient)

Witnesses:

1, I am a competent adult who is not named as the agent. _____
I witnessed the patient's signature on this form. Signature of witness number 1

2. I am a competent adult who is not named as the agent. _____
I am not related to the patient by blood, marriage, or adoption and I would not be entitled to any portion of the patient's estate upon his or her death under any existing will or codicil or by operation of law. I witnessed the patient's signature on this form. Signature of witness number 2

This document may be notarized instead of witnessed: _____

STATE OF TENNESSEE
COUNTY OF _____

I am a Notary Public in and for the State and County named above. The person who signed this instrument is personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who signed as the "patient". The patient personally appeared before me and signed above or acknowledged the signature above as his or her own. I declare under penalty of perjury that the patient appears to be of sound mind and under no duress, fraud, or undue influence.

My commission expires: _____

(Rule 1200-08-10-.15 continued)

Signature of Notary Public

WHAT TO DO WITH THIS ADVANCE DIRECTIVE

- Provide a copy to your physician(s)
- Keep a copy in your personal files where it is accessible to others
- Tell your closest relatives and friends what is in the document
- Provide a copy to the person(s) you named as your health care agent

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005
Acknowledgement to Project GRACE for inspiring the development of this form.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-11-224, and 68-11-1805.

Administrative History: Original rule filed February 16, 2007; effective May 2, 2007.