

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

**CHAPTER 1200-08-35
STANDARDS FOR OUTPATIENT DIAGNOSTIC CENTERS**

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1200-08-35-.01 DEFINITIONS.

- (1) Abuse. The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.
- (2) Acceptable Plan of Correction. The Licensing Division approves an Outpatient Diagnostic Center's plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:
 - (a) How the deficiency will be corrected.
 - (b) Who will be responsible for correcting the deficiency.
 - (c) The date the deficiency will be corrected.
 - (d) How the facility will prevent the same deficiency from re-occurring.
- (3) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.
- (4) Adult. An individual who has capacity and is at least 18 years of age.
- (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) 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.
- (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

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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) Cardiac Catheterization. An invasive procedure in which a transluminal catheter is inserted into the femoral, internal jugular or antecubital vein and guided through the venous system into the heart chambers and/or coronary arteries while the patient is under conscious sedation in order to provide anatomic information on the heart chambers, coronary arteries, valves, myocardium, and the great vessels.
- (11) 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.
- (12) 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.
- (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.
- (17) Computerized Tomography. A non-invasive radiological diagnostic procedure that may or may not include nuclear medical dye.
- (18) Conscious Sedation. A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patient airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.
- (19) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.
- (20) Department. The Tennessee Department of Health.
- (21) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.
- (22) Do-Not-Resuscitate Order (DNR). A written order, other than a POST, not to resuscitate a patient in cardiac or respiratory arrest in accordance with accepted medical practices.

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- (23) **Electronic Signature.** The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.
- (24) **Emancipated Minor.** Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.
- (25) **Emergency Responder.** A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.
- (26) **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 Anesthetists' Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.
- (27) **Guardian.** A judicially appointed guardian or conservator having authority to make a health care decision for an individual.
- (28) **Hazardous Waste.** Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.
- (29) **Health Care.** Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).
- (30) **Health Care Decision.** Consent, refusal of consent or withdrawal of consent to health care.
- (31) **Health Care Decision-maker.** In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-35-.13 or T.C.A. § 33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.
- (32) **Health Care Institution.** A health care institution as defined in T.C.A. § 68-11-1602.
- (33) **Health Care Provider.** A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.
- (34) **Incompetent.** A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.
- (35) **Individual instruction.** An individual's direction concerning a health care decision for the individual.
- (36) **Infectious Waste.** Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.
- (37) **Licensed Practical Nurse.** A person currently licensed as such by the Tennessee Board of Nursing.

(Rule 1200-08-35-.01, continued)

- (38) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules and regulations.
- (39) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (40) Lithotripsy. A technique using extracorporeal shock waves to break up stones that form in the kidney, bladder, ureters, or gallbladder while monitoring through x-ray or ultrasound.
- (41) Magnetic Resonance Imaging (MRI). A non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.
- (42) Mammography. A non-invasive radiological procedure used to take pictures of the breasts in order to diagnose tumors or cysts.
- (43) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.
- (44) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.
- (45) Medical Staff. An organized body composed of individuals appointed by the Outpatient Diagnostic Center governing board. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.
- (46) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.
- (47) Mid-Level Practitioner. A registered nurse licensed in Tennessee who holds a master's degree in a clinical nursing specialty, national certification through the ANCC or American Academy of Nurse Practitioners and holds a certificate of fitness to prescribe from the Tennessee Board of Nursing.
- (48) Misappropriation of Patient/Resident Property. The deliberate misplacement, exploitation or wrongful, temporary or permanent use of an individual's belongings or money without the individual's consent.
- (49) Neglect. The failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of the living will, shall not be deemed "neglect" for purposes of these rules.
- (50) N.F.P.A. National Fire Protection Association.

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- (51) 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.
- (52) Outpatient Diagnostic Center. Any facility providing outpatient diagnostic services (computerized tomography, magnetic resonance imaging, positron emission tomography, or other imaging technology developed after June 9, 2005 which provides substantially the same functionality), unless the outpatient diagnostic services are provided as the services of another licensed healthcare institution that reports such outpatient diagnostic services on its joint annual report, or the facility is otherwise excluded from this definition. Outpatient diagnostic center does not include a physician or dental practice that is conducted at a location occupied and controlled by one or more physicians or dentists licensed under Title 63, if the outpatient diagnostic services are ancillary to the specialties of the physicians' practice or are provided primarily for persons who are patients of the physicians or dentists in the practice for purposes other than outpatient diagnostic services. Outpatient diagnostic centers in existence prior to the effective date of this rule will be required to obtain licensure by the department of health and comply with relevant reporting requirements.
- (53) 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.
- (54) Percutaneous Transluminal Coronary Angioplasty. An invasive diagnostic procedure in which a transluminal catheter is guided through the femoral, subclavian, internal jugular or antecubital vein allowing the passage of a balloon-tipped catheter distally into the coronary artery while viewing through radiological pictures. The balloon is aligned within the stenosis and inflated to dilate the vessel with or without the use of anticoagulants to reduce the incidence of thrombosis at the site of balloon dilation and calcium blockers or nitrates to reduce coronary spasm. Conscious sedation and local anesthesia at catheter insertion site are utilized during the procedure.
- (55) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
- (56) Personally Informing. A communication by any effective means from the patient directly to a health care provider.
- (57) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.
- (58) Physician Assistant. A person who has graduated from a physician assistant educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a physician assistant under title 63, chapter 19.
- (59) Physician Orders for Scope of Treatment or POST. Written orders that:
 - (a) Are on a form approved by the Board for Licensing Health Care Facilities;
 - (b) Apply regardless of the treatment setting and that are signed as required herein by the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist; and

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(c)

1. Specify whether, in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should or should not be attempted;
 2. Specify other medical interventions that are to be provided or withheld; or
 3. Specify both 1 and 2.
- (60) Positron Emission Tomography (PET Scan). A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography.
- (61) 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.
- (62) 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.
- (63) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.
- (64) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.
- (65) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.
- (66) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.
- (67) Shall or Must. Compliance is mandatory.
- (68) 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.
- (69) Stereotactic Procedure. An invasive technique utilized for precisely directing the tip of a delicate needle or beam of radiation in three planes using coordinates provided by medical imaging such as x-ray or CT scan in order to reach a specific location in the body, eg. tumor.
- (70) 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.
- (71) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (72) 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.
- (73) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

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- (74) Vascular Embolization. Therapeutic introduction of various substances into the circulation to occlude vessels, either to arrest or prevent hemorrhaging, to devitalize a structure, tumor or organ by occluding its blood supply or to reduce blood flow to an arteriovenous malformation.

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, 68-11-211, 68-11-216, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.

1200-08-35-.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 outpatient diagnostic center as defined, without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the outpatient diagnostic center.
- (2) In order to make application for a license:
- (a) The applicant shall submit an application on a form prepared by the department.
 - (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand four hundred and four dollars (\$1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.
 - (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the Outpatient Diagnostic Center until a license has been issued. Applicants shall not hold themselves out to the public as being an Outpatient Diagnostic Center 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.
 - (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 outpatient diagnostic 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 Outpatient Diagnostic Center, when issued a license, shall be classified according to the type of services rendered or category of patients served. The Outpatient Diagnostic Center 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.

(Rule 1200-08-35-.02, continued)

- (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 the purposes of licensing, the licensee of an Outpatient Diagnostic Center 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 Outpatient Diagnostic Center 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;
 - 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.

(Rule 1200-08-35-.02, continued)

- (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 leasee, who shall continue the operation, retains the same legal form as the former owner.
- (5) Renewal.
- (a) In order to renew a license, each outpatient diagnostic 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; provided that the late penalty shall not exceed twice the renewal fee.
 - (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 - 1. A completed application for licensure;
 - 2. The license fee provided in rule 1200-08-35-.02(2)(b); and
 - 3. Any other information required by the Health Services and Development Agency.
 - (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206(a)(5), 68-11-206, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, § 1.
Administrative History: Original rule filed October 26, 2005; effective January 9, 2006. 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. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed March 26, 2019; effective June 24, 2019.

1200-08-35-.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 Outpatient Diagnostic Center;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the Outpatient Diagnostic Center; and
 - (e) Failure to renew license.

(Rule 1200-08-35-.03, continued)

- (2) The board may consider all factors that 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 Outpatient Diagnostic 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 plan of correction indicating the following:
 - (a) How the deficiency will be corrected;
 - (b) The date upon which each deficiency will be corrected;
 - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
 - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.
- (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 Outpatient Diagnostic 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.

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, 68-11-207, 68-11-208, 68-11-209, and 68-11-216. **Administrative History:** Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed March 1, 2007; effective May 15, 2007.

1200-08-35-.04 ADMINISTRATION.

- (1) The Outpatient Diagnostic Center must have an effective governing body legally responsible for the conduct of the Outpatient Diagnostic Center. If an Outpatient Diagnostic Center does not have an organized governing body, the persons legally responsible for the conduct of the Outpatient Diagnostic Center must carry out the functions specified in this chapter.
- (2) The governing body or individual responsible shall appoint a chief executive officer or administrator who is responsible for managing the Outpatient Diagnostic Center. The chief executive officer or administrator shall designate an individual to act for him or her in his or

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her absence, in order to provide the Outpatient Diagnostic Center with administrative direction at all times.

- (3) 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.
- (4) The governing body or individual responsible, 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.
- (5) The governing body or individual responsible shall assure that the Outpatient Diagnostic Center has the financial resources to provide the services essential to the operation of the facility.
- (6) Staffing shall be adequate to provide the services essential to the operation of the Outpatient Diagnostic Center.
- (7) The Outpatient Diagnostic Center shall assess and provide adequate comfort measures as needed.
- (8) The Outpatient Diagnostic Center shall perform only those diagnostic procedures which can be safely and effectively carried out on an outpatient basis.
- (9) Each Outpatient Diagnostic Center shall have at all times a licensed physician 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 Outpatient Diagnostic Center which violates a required policy also violates the rule and regulation establishing the requirement.
- (13) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (14) No Outpatient Diagnostic Center 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 Outpatient Diagnostic Center 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, laboratory or therapy services are purchased from others, the governing body or responsible individual shall be responsible to assure the

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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 or responsible individual 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 or responsible individual 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) All health care facilities licensed pursuant to T.C.A. § 68-11-201 shall post the following in the main public entrance:
 - (a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;
 - (b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and
 - (c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

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

- (19) "No smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.
- (20) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-17-1803, 39-17-1805, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268, and 71-6-121. **Administrative History:** Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed February 22, 2010; effective May 23, 2010.

1200-08-35-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

- (1) All procedures provided in an Outpatient Diagnostic Center shall be ordered by a physician. The name, address and telephone number of the ordering physician shall be recorded in the patient's medical record.
- (2) Diagnostic testing in outpatient diagnostic centers may be ordered by the following:
 - (a) Any Tennessee practitioner licensed under Title 63 who is authorized to do so by his or her practice act;
 - (b) Any out of state practitioner who has a Tennessee telemedicine license issued pursuant to rule 0880-02-.16; or

(Rule 1200-08-35-.05, continued)

- (c) Any duly licensed out of state health care professional who is authorized by his or her state board to order outpatient diagnostic testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-02-.14(7)(a)1., 2., and 3.
- (3) 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.
- (4) For purposes of this chapter, and when applicable, the requirements for signature or countersignature by a physician 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 Outpatient Diagnostic Center protocol or rules.
- (5) The Outpatient Diagnostic Center shall have available a plan for emergency transportation to a licensed local hospital.
- (6) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post procedural 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 October 26, 2005; effective January 9, 2006.

1200-08-35-.06 BASIC SERVICES.

- (1) Radiological services. If laboratory tests are performed in the nuclear medicine services, they shall meet applicable requirements for laboratory services as specified in T.C.A. § 68-29-101 *et seq.*
 - (a) Radiological services provided shall be maintained free of hazards for patients and personnel.
 - (b) 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.
 - (c) Patients, employees and the general public shall be provided protection from radiation in accordance with "State Regulations for Protection Against Radiation". All radiation producing equipment shall be registered and all radioactive material shall be licensed by the Division of Radiological Health of the Tennessee Department of Environment and Conservation.
 - (d) Periodic inspections of equipment must be made and hazards identified must be promptly corrected.
 - (e) Radiology personnel shall be qualified by education, training and experience for the type of service rendered.
 - (f) X-rays shall be retained for four (4) years and may be retired thereafter provided that a signed interpretation by a radiologist is maintained in the patient's record under T.C.A. § 68-11-305.

(Rule 1200-08-35-.06, continued)

- (g) Patient safety shall be ensured in all areas of the facility.
 - (h) Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.
 - (i) In-house preparation of radiopharmaceuticals shall be accomplished by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.
 - (j) The Outpatient Diagnostic Center shall maintain records of the receipt and disposition of radiopharmaceuticals.
- (2) Invasive Procedures.
- (a) If the facility provides invasive diagnostic procedures eg. cardiac catheterization, percutaneous transluminal coronary angioplasty, vascular embolization or stereotactic procedures using anesthesia, the services must be well organized and provided in accordance with acceptable standards of practice.
 - (b) A qualified registered nurse shall be present during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.
 - (c) Properly executed informed consent forms shall be in the patient's chart before procedure is performed, except in emergencies.
 - (d) Adequate equipment and supplies shall be available to the invasive diagnostic room and to the post procedure care area. The following equipment and supplies shall be provided for cardiac catheterization or angioplasty:
 - 1. Call-in system
 - 2. Cardiac monitor
 - 3. Pulse Oximeter
 - 4. Resuscitator
 - 5. Defibrillator
 - 6. Aspirator
 - 7. Tracheotomy set
 - (e) A crash cart must be available with appropriate medications.
 - (f) A qualified registered nurse shall be in the post procedure area during the patient's recovery period during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.
 - (g) A report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following the procedure and signed by the physician.
 - (h) The Outpatient Diagnostic Center shall provide one or more procedure rooms which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.

(Rule 1200-08-35-.06, continued)

- (3) Anesthesia. General anesthesia shall not be administered in Outpatient Diagnostic Centers.
 - (a) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the governing body, or responsible individual.
 - (b) 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 shall also be on file.
 - (c) 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.
- (4) Pharmaceutical Services. The Outpatient Diagnostic Center must provide drugs and biologicals in a safe and effective manner in accordance with accepted federal and state standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.
- (5) 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.

(Rule 1200-08-35-.06, continued)

- (c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.
 - (d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.
 - (e) Safety issues shall be addressed and resolved.
 - (f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.
 - (g) The building and grounds shall be suitable to services provided and patients served.
- (6) Medical Records.
- (a) The Outpatient Diagnostic Center 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 services provided by the Outpatient Diagnostic Center 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. Operative report;
 - 7. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,
 - 8. Radiology 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.
- (7) Infection Control.
- (a) The Outpatient Diagnostic Center 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 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.

(Rule 1200-08-35-.06, continued)

- (c) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.
 - (d) All Outpatient Diagnostic Center'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.
 - (e) An Outpatient Diagnostic Center shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Outpatient Diagnostic Center will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 - 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.
 - (f) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.
 - (g) Any condition on the facility 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.
- (8) Performance Improvement. The Outpatient Diagnostic Center shall have a planned, systematic, organization-wide approach to process design and redesign, performance measurement, assessment and improvement which is approved by the designated governing body or responsible individual. This plan shall address and/or include, but is not limited to:
- (a) Infection control, including post-operative surveillance;
 - (b) Complications of procedures;
 - (c) Documentation of periodic review of the data collected and follow-up actions;

(Rule 1200-08-35-.06, continued)

- (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.
- (9) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, dietary, environmental, nursing, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.
- (10) Laboratory Services.
- (a) The Outpatient Diagnostic Center 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 Outpatient Diagnostic Center.
 - (b) Any patient terminating pregnancy in an Outpatient Diagnostic Center 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.
- (11) 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.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed October 20, 2015; effective January 18, 2016. Amendments filed July 18, 2016; effective October 16, 2016.

1200-08-35-.07 RESERVED.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006.

1200-08-35-.08 BUILDING STANDARDS.

- (1) An ODC shall construct, arrange, and maintain the condition of the physical plant and the overall ODC environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.

(Rule 1200-08-35-.08, continued)

- (4) The licensed contractor shall perform all new construction and renovations to ODCs, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in ODCs, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new ODC shall be constructed, nor shall major alterations be made to an existing ODC without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ODC is licensed or before any alteration or expansion of a licensed ODC 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 licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.
- (6) 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.
- (7) 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. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the department requires.
 - (a) The project architect or engineer shall forward two (2) sets of plans 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 owner's understanding that such work is at the owner's own risk and without assurance that final approval of final plans and specifications shall be granted. The project architect or engineer shall submit final plans and specifications for review and approval. The department must grant final approval before the project proceeds beyond foundation work.
 - (b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.
- (8) 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 $8\frac{1}{2} \times 11$ inch folder.
- (9) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical, Electrical and Sprinkler.
- (10) Architectural drawings shall include where applicable:
 - (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 1200-08-35-.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.
- (11) Structural drawings shall include where applicable:
- (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.
- (12) Mechanical drawings shall include where applicable:
- (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.
- (13) Electrical drawings shall include where applicable:
- (a) A seal, certifying that all electrical work and equipment is in compliance with all applicable codes 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 1200-08-35-.08, continued)

- (c) An electrical system that complies with applicable codes;
 - (d) Color coding to show all items on emergency power;
 - (e) Circuit breakers that are properly labeled; and
 - (f) Ground-Fault Circuit Interrupters (GFCI) that are required in all wet areas, such as kitchens, laundries, janitor closets, bath and toilet rooms, etc, and within six (6) feet of any lavatory.
- (14) The electrical drawings shall not include knob and tube wiring, shall not include electrical cords that have splices, and shall not show that the electrical system is overloaded.
- (15) In all new facilities or renovations to existing electrical systems, the installation must be approved by an inspector or agency authorized by the State Fire Marshal.
- (16) Sprinkler drawings shall include where applicable:
- (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.
- (17) The licensed contractor shall not install a system of water supply, plumbing, sewage, garbage or refuse disposal nor materially alter or extend any existing system until the architect or engineer submits complete plans and specifications for the installation, alteration or extension to the department demonstrating that all applicable codes have been met and the department has granted necessary approval.
- (a) Before the ODC is used, Tennessee Department of Environment and Conservation shall approve the water supply system.
 - (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.
- (18) It shall be demonstrated through the submission of plans and specifications that in each ODC 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.
- (19) The department shall acknowledge that it has reviewed plans and specifications in writing with copies sent to the project architect, the project engineer, the owner, the manager or other executive of the institution. The department may modify the distribution of such review at its discretion.

(Rule 1200-08-35-.08, continued)

- (20) In the event submitted materials do not appear to satisfactorily comply with 1200-08-35-.08(2), 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.
- (21) The licensed contractor shall execute all construction in accordance with the approved plans and specifications.
- (22) If construction begins within one hundred eighty (180) days of the date of department approval, the department's written notification of satisfactory review constitutes compliance with 1200-08-35-.08(2). 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.
- (23) Prior to final inspection, a CD Rom disc, in TIF or PDF format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.
- (24) The department requires the following alarms that shall be monitored twenty-four (24) hours per day:
 - (a) Fire alarms; and
 - (b) Generators (if applicable).
- (25) 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.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006. Repeal and new rule filed December 20, 2011; effective March 19, 2012. Amendment filed January 21, 2016; effective April 20, 2016.

1200-08-35-.09 LIFE SAFETY.

- (1) Any outpatient diagnostic 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 outpatient diagnostic 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 October 26, 2005; effective January 9, 2006.

1200-08-35-.10 INFECTIOUS AND HAZARDOUS WASTE.

- (1) Each Outpatient Diagnostic 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;
 - (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 procedures;
 - (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;

(Rule 1200-08-35-.10, continued)

- (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.
 - (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;
 - (c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done; and
 - (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.

(Rule 1200-08-35-.10, continued)

Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

- (b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. § 69-3-101 et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.
 - (c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.
- (9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.
- (10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.
- (11) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006.

1200-08-35-.11 RECORDS AND REPORTS.

- (1) The Joint Annual Report of Outpatient Diagnostic Centers shall be filed with the department. The forms are furnished and mailed to each Outpatient Diagnostic Center by the department each year and the forms must be completed and returned to the department as required.
- (2) The facility shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.
- (3) The Outpatient Diagnostic Center shall report to the department each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of an Outpatient Diagnostic Center's license.
- (4) The outpatient diagnostic center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(Rule 1200-08-35-.11, continued)

- (5) The outpatient diagnostic center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.
 - (a) Strike by staff at the facility;
 - (b) External disasters impacting the facility;
 - (c) Disruption of any service vital to the continued safe operation of the outpatient diagnostic center or to the health and safety of its patients and personnel; and
 - (d) Fires at the outpatient diagnostic center that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

- (6) Legible copies of the following records and reports shall be retained in the Outpatient Diagnostic Center, shall be maintained in a single file, and shall be made available for inspection during normal business hours to any patient who requests to view them for thirty-six (36) months following their issuance:
 - (a) Local fire safety inspections;
 - (b) Local building code inspections, if any;
 - (c) Fire marshal reports;
 - (d) Department licensure and fire safety inspections and surveys;
 - (e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;
 - (f) Federal Center for Medicare and Medicaid Services surveys and inspections, if any;
 - (g) Orders of the Commissioner or Board, if any;
 - (h) Comptroller of the Treasury's audit reports and findings, if any;
 - (i) Maintenance records of all safety equipment; and
 - (j) Radiological inspection reports.

- (7) Copies of patient's medical records shall be maintained for at least ten (10) years.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, and 68-11-216. **Administrative History:** Original rule filed October 26, 2005; effective January 9, 2006. Amendments filed January 3, 2012; effective April 2, 2012.

1200-08-35-.12 PATIENT RIGHTS.

- (1) Each patient has at least the following rights:
 - (a) To privacy in treatment and personal care;
 - (b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

(Rule 1200-08-35-.12, continued)

- (c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;
 - (d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;
 - (e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The outpatient diagnostic center must have policies to govern access and duplication of the patient's record;
 - (f) To have appropriate assessment and management of pain; and
 - (g) To be involved in the decision making of all aspects of their care.
- (2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.
Administrative History: Original rule filed October 26, 2005; effective January 9, 2006.

1200-08-35-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

- (1) Pursuant to this Rule, each outpatient diagnostic center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.
- (2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.
- (3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.
- (4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.
- (5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(Rule 1200-08-35-.13, continued)

- (6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.
- (7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.
- (8) An advance directive may include the individual's nomination of a court-appointed guardian.
- (9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.
- (10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.
- (11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.
- (12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.
- (13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.
- (14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.
- (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

(Rule 1200-08-35-.13, continued)

3. The agent or guardian is not reasonably available.
- (c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.
 - (d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.
 - (e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:
 1. The patient's spouse, unless legally separated;
 2. The patient's adult child;
 3. The patient's parent;
 4. The patient's adult sibling;
 5. Any other adult relative of the patient; or
 6. Any other adult who satisfies the requirements of 1200-08-35-.13(16)(d).
 - (f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.
 - (g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:
 1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;
 2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;
 3. The proposed surrogate's demonstrated care and concern;
 4. The proposed surrogate's availability to visit the patient during his or her illness; and
 5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.
 - (h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-35-.13(16)(c) through 1200-08-35-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:
 1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

(Rule 1200-08-35-.13, continued)

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.
 - (i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.
 - (j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.
 - (k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.
 - (l) Except as provided in 1200-08-35-.13(16)(m):
 1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and
 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.

(Rule 1200-08-35-.13, continued)

- (c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.
- (18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.
- (19) Except as provided in 1200-08-35-.13(20) through 1200-08-35-.13(22), a health care provider or institution providing care to a patient shall:
- (a) Comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and
 - (b) Comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.
- (20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.
- (21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:
- (a) Contrary to a policy of the institution which is based on reasons of conscience, and
 - (b) The policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.
- (22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.
- (23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-35-.13(20) through 1200-08-35-.13(22) shall:
- (a) Promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;
 - (b) Provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;
 - (c) Unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and
 - (d) If a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(Rule 1200-08-35-.13, continued)

- (24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.
- (25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:
 - (a) Complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;
 - (b) Declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or
 - (c) Complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.
- (26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.
- (27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.
- (28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.
- (29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.
- (30) Physician Orders for Scope of Treatment (POST)
 - (a) Physician Orders for Scope of Treatment (POST) may be issued by a physician for a patient with whom the physician has a bona fide physician-patient relationship, but only:
 - 1. With the informed consent of the patient;
 - 2. If the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon 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, if the physician determines that the provision of cardio pulmonary resuscitation would be contrary to accepted medical standards.
 - (b) A POST may be issued by a physician assistant, nurse practitioner or clinical nurse specialist for a patient with whom such physician assistant, nurse practitioner or clinical nurse specialist has a bona fide physician assistant-patient or nurse-patient relationship, but only if:

(Rule 1200-08-35-.13, continued)

1. No physician, who has a bona fide physician-patient relationship with the patient, is present and available for discussion with the patient (or if the patient is a minor or is otherwise incapable of making an informed decision, with the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act);
 2. Such authority to issue is contained in the physician assistant's, nurse practitioner's or clinical nurse specialist's protocols;
 3. Either:
 - (i) The patient is a resident of a nursing home licensed under title 68 or an ICF/MR facility licensed under title 33 and is in the process of being discharged from the nursing home or transferred to another facility at the time the POST is being issued; or
 - (ii) The patient is a hospital patient and is in the process of being discharged from the hospital or transferred to another facility at the time the POST is being issued; and
 4. Either:
 - (i) With the informed consent of the patient;
 - (ii) If the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon 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
 - (iii) 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 and such authority to issue is contained in the physician assistant, nurse practitioner or clinical nurse specialist's protocols and the physician assistant or nurse determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.
- (c) 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 any contrary order in the POST. 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 any contrary order in the POST. Nothing in this section shall be construed to require cardiopulmonary resuscitation of a patient for whom the physician or physician assistant or nurse practitioner or clinical nurse specialist determines cardiopulmonary resuscitation is not medically appropriate.
- (d) A POST issued in accordance with this section shall remain valid and in effect until revoked. In accordance with this rule and applicable regulations, 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, the Department of Mental Health and Substance Abuse Services, or the Department of Intellectual and Developmental Disabilities, or operated, licensed, or owned by another state agency, shall follow a POST that is available to such persons in a form approved by the Board for Licensing Health Care Facilities.

(Rule 1200-08-35-.13, continued)

- (e) Nothing in these rules shall authorize the withholding of other medical interventions, such as medications, positioning, wound care, oxygen, suction, treatment of airway obstruction or other therapies deemed necessary to provide comfort care or alleviate pain.
- (f) If a person has a do-not-resuscitate order in effect at the time of such person's discharge from a health care facility, the facility shall complete a POST prior to discharge. If a person with a POST 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 POST to qualified emergency medical service personnel and to the receiving facility prior to the transfer. The transferring facility shall provide a copy of the POST that accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the POST a part of the patient's record.
- (g) These rules shall not prevent, prohibit, or limit a physician from using a written order, other than a POST, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices. This action shall have no application to any do not resuscitate order that is not a POST, as defined in these rules.
- (h) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to then-current law, shall remain valid and shall be given effect as provided in these rules.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1803, 68-11-1804, 68-11-1805, 68-11-1806 through 68-11-1810, 68-11-1813, and 68-11-1814.
Administrative History: Original rule filed October 26, 2005; effective January 9, 2006. Amendments filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.

1200-08-35-.14 DISASTER PREPAREDNESS.

- (1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans and the specific emergency numbers related to that type of disaster shall be readily available at all times. Each of the following plans shall be exercised annually:
 - (a) Fire Safety Procedures Plan shall include:
 - 1. Minor fires;
 - 2. Major fires;
 - 3. Fighting the fire;
 - 4. Evacuation procedures;
 - 5. Staff functions.
 - (b) Tornado/Severe Weather Procedures Plan shall include:

(Rule 1200-08-35-.14, continued)

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

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006.

1200-08-35-.15 APPENDIX I

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

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(Rule 1200-08-35-.15, continued)

A COPY OF THIS FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED			
Tennessee Physician Orders for Scope of Treatment (POST, sometimes called "POLST")		Patient's Last Name	
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, then contact physician.		First Name/Middle Initial	
		Date of Birth	
Section A <i>Check One Box Only</i>	CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse <u>and</u> is not breathing. <input type="checkbox"/> Resuscitate(CPR) <input type="checkbox"/> Do Not Attempt Resuscitation (DNR / no CPR) (Allow Natural Death) When not in cardiopulmonary arrest, follow orders in B, C, and D.		
Section B <i>Check One Box Only</i>	MEDICAL INTERVENTIONS. Patient has pulse <u>and/or</u> is breathing. <input type="checkbox"/> Comfort Measures Only. Relieve pain and suffering through the use of any medication by any route, positioning, wound care and other measures. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Do not transfer to hospital for life-sustaining treatment. Transfer only if comfort needs cannot be met in current location. Treatment Plan: Maximize comfort through symptom management. <input type="checkbox"/> Limited Additional Interventions. In addition to care described in Comfort Measures Only above, use medical treatment, antibiotics, IV fluids and cardiac monitoring as indicated. No intubation, advanced airway interventions, or mechanical ventilation. May consider less invasive airway support (e.g. CPAP, BiPAP). Transfer to hospital if indicated. Generally avoid the intensive care unit. Treatment Plan: basic medical treatments. <input type="checkbox"/> Full Treatment. In addition to care described in Comfort Measures Only and Limited Additional Interventions above, use intubation, advanced airway interventions, and mechanical ventilation as indicated. Transfer to hospital and/or intensive care unit if indicated. Treatment Plan: Full treatment including in the intensive care unit. <i>Other Instructions:</i> _____		
Section C <i>Check One</i>	ARTIFICIALLY ADMINISTERED NUTRITION. Oral fluids & nutrition must be offered if feasible. <input type="checkbox"/> No artificial nutrition by tube. <input type="checkbox"/> Defined trial period of artificial nutrition by tube. <input type="checkbox"/> Long-term artificial nutrition by tube. <i>Other Instructions:</i> _____		
Section D <i>Must be Completed</i>	Discussed with: <input type="checkbox"/> Patient/Resident <input type="checkbox"/> Health care agent <input type="checkbox"/> Court-appointed guardian <input type="checkbox"/> Health care surrogate <input type="checkbox"/> Parent of minor <input type="checkbox"/> Other: _____ (Specify)	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) <input type="checkbox"/> Medical indications <input type="checkbox"/> (Other) _____	
Physician/NP/CNS/PA Name (Print)		Physician/NP/CNS/PA Signature	Date
		MD/NP/CNS/PA Phone Number:	
		NP/CNS/PA (Signature at Discharge)	
Signature of Patient, Parent of Minor, or Guardian/Health Care Representative			
Preferences have been expressed to a physician and/or health care professional. It can be reviewed and updated at any time if your preferences change. If you are unable to make your own health care decisions, the orders should reflect your preferences as best understood by your surrogate.			
Name (print)		Signature	Relationship (write "self" if patient)

(Rule 1200-08-35-.15, continued)

Agent/Surrogate	Relationship	Phone Number	
Health Care Professional Preparing Form	Preparer Title	Phone Number	Date Prepared

HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY

Directions for Health Care Professionals

Completing POST

Must be completed by a health care professional based on patient preferences, patient best interest, and medical indications.

To be valid, POST must be signed by a physician or, at discharge or transfer from a hospital or long term care facility, by a nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA). Verbal orders are acceptable with follow-up signature by physician in accordance with facility/community policy.

Persons with DNR in effect at time of discharge must have POST completed by health care facility prior to discharge and copy of POST provided to qualified medical emergency personnel.

Photocopies/faxes of signed POST forms are legal and valid.

Using POST

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 must always be offered 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 Health Care Agent or Surrogate of a person without capacity, can request alternative treatment.

Reviewing POST

This POST should be reviewed if:

- (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 D and write "VOID" in large letters if POST is replaced or becomes invalid.

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED.

(Rule 1200-08-35-.15, continued)

(2) Advance Directive for Health Care Form

ADVANCE DIRECTIVE FOR HEALTH CARE*
(Tennessee)**Instructions:** Parts 1 and 2 may be used together or independently. Please mark out/void any unused part(s). Part 5, Block A or Block B must be completed for all uses.

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.

Part I Agent: I want the following person to make health care decisions for me. This includes any health care decision I could have made for myself if able, except that my agent must follow my instructions below:

Name: _____ Relation: _____ Home Phone: _____ Work Phone: _____
Address: _____ Mobile Phone: _____ Other Phone: _____

Alternate Agent: If the person named above is unable or unwilling to make health care decisions for me, I appoint as alternate the following person to make health care decisions for me. This includes any health care decision I could have made for myself if able, except that my agent must follow my instructions below:

Name: _____ Relation: _____ Home Phone: _____ Work Phone: _____
Address: _____ Mobile Phone: _____ Other Phone: _____

My agent is also my personal representative for purposes of federal and state privacy laws, including HIPAA.

When Effective (mark one): I give my agent permission to make health care decisions for me at any time, even if I have capacity to make decisions for myself. I do not give such permission (this form applies only when I no longer have capacity).

Part 2 Indicate Your Wishes for Quality of Life: By marking “yes” below, I have indicated conditions I would be willing to live with if given adequate comfort care and pain management. By marking “no” below, I have indicated conditions I would not be willing to live with (that to me would create an **unacceptable** quality of life).

<input type="checkbox"/>	<input type="checkbox"/>	Permanent Unconscious Condition: I become totally unaware of people or surroundings with little chance of ever waking up from the coma.
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	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.
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Dependent in all Activities of Daily Living: I am no longer able to talk or communicate clearly or move by myself. I depend on others for feeding, bathing, dressing, and walking. Rehabilitation or any other restorative treatment will not help.
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	End-Stage Illnesses: I have an illness that has reached its final stages in spite of full treatment. Examples: Widespread cancer that no longer responds to treatment; chronic and/or damaged heart and lungs, where oxygen is needed most of the time and activities are limited due to the feeling of suffocation.
Yes	No	

Indicate Your Wishes for Treatment: If my quality of life becomes unacceptable to me (as indicated by one or more of the conditions marked “no” above) and my condition is irreversible (that is, it will not improve), I direct that medically appropriate treatment be provided as follows. By marking “yes” below, I have indicated treatment I want. By marking “no” below, I have indicated treatment I **do not want**.

(Rule 1200-08-35-.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 a patient's stomach or use of IV fluids into a vein, which would include artificially delivered nutrition and hydration.
Yes	No	

Part 3 Other instructions, such as hospice care, burial arrangements, etc.: _____

(Attach additional pages if necessary)

Part 4 Organ donation: Upon my death, I wish to make the following anatomical gift for purposes of transplantation, research, and/or education (mark one):

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

 No organ/tissue donation

SIGNATURE

Part 5 Your signature must **either** be witnessed by two competent adults ("Block A") **or** by a notary public ("Block B").

Signature: _____ Date: _____
 (Patient)

Block A Neither witness may be the person you appointed as your agent or alternate, and at least one of the witnesses must be someone who is not related to you or entitled to any part of your estate.

Witnesses:

1. I am a competent adult who is not named as the agent or alternate. 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 or alternate. 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

Block B You may choose to have your signature witnessed by a notary public instead of the witnesses described in Block A.

STATE OF TENNESSEE

(Rule 1200-08-35-.15, continued)

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: _____

Signature of Notary Public

WHAT TO DO WITH THIS ADVANCE DIRECTIVE: (1) provide a copy to your physician(s); (2) keep a copy in your personal files where it is accessible to others; (3) tell your closest relatives and friends what is in the document; and (4) provide a copy to the person(s) you named as your health care agent.

* This form replaces the old forms for durable power of attorney for health care, living will, appointment of agent, and advance care plan, and eliminates the need for any of those documents.

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 August 28, 2012; effective November 26, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendments filed February 8, 2017; effective May 9, 2017.