Department of Health
Rulemaking Hearing Rules
Board for Licensing Health Care Facilities

Chapter 1200-8-35
Standards for Outpatient Diagnostic Centers

New Rules

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1200-8-35-.01 Definitions.

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

(a) How the deficiency will be corrected.

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

(c) The date the deficiency will be corrected.

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

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Adult. An individual who has capacity and is at least 18 years of age.

(4) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(5) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

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

(7) Cancer Treatment and Radiation Clinic. A facility in which the only procedures performed are diagnostic and therapeutic radiology, chemotherapy and related services.

(8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(9) Cardiac Catheterization. An invasive procedure in which a transluminal catheter is inserted into the femoral, internal jugular or antecubital vein and guided through the venous system into the heart chambers and/or coronary arteries while the patient is under conscious sedation in order to provide anatomic information on the heart chambers, coronary arteries, valves, myocardium, and the great vessels.

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

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

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

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

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

(15) Competent. A patient who has capacity.

(16) Computerized Tomography. A non-invasive radiological diagnostic procedure that may or may not include nuclear medical dye.

(17) Conscious Sedation. A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patient airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.

(18) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual incident,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(19) 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 (DNR) Order. An order entered by the patient's treating physician in the patient's medical records which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation.

(23) 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 Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(27) 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 1200-8-35-.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.

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

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

(50) Outpatient Diagnostic Center. Any agency, institution, facility or place which primarily performs diagnostic procedures on an outpatient basis only.

(51) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(52) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(53) Percutaneous Transluminal Coronary Angioplasty. An invasive diagnostic procedure in which a transluminal catheter is guided through the femoral, subclavian, internal jugular or antecubital vein allowing the passage of a balloon-tipped catheter distally into the coronary artery while viewing through radiological pictures. The balloon is aligned within the stenosis and inflated to dilate the vessel with or without the use of anticoagulants to reduce the incidence of thrombosis at the site of balloon dilation and calcium blockers or nitrates to reduce coronary spasm. Conscious sedation and local anesthesia at catheter insertion site are utilized during the procedure.

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

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

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

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

(58) Positron Emission Tomography (PET Scan). A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography.

(59) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(60) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other

emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(61) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.

(62) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(63) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.

(64) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.

(65) Shall or Must. Compliance is mandatory.

(66) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(67) Stereotactic Procedure. An invasive technique utilized for precisely directing the tip of a delicate needle or beam of radiation in three planes using coordinates provided by medical imaging such as x-ray or CT scan in order to reach a specific location in the body, eg. tumor.

(68) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

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

(70) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

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

(72) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's

physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities shall serve as a Universal DNR according to these rules.

(73) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

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

(75) 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, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-224, and 68-11-1802.

1200-8-35-.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 applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30. The license shall be posted in a conspicuous place in the 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 eight hundred dollars ($800). The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the

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.

(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.

(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) Circumstances constituting a change of ownership may include, but are not limited to, the following:

1. Partnership. In the case of a partnership, the removal, addition, or substitution of a partner constitutes a change of ownership. If the facility is owned by a limited partnership, the removal of the general partner or general partners constitutes a change of ownership.

2. Corporation. The merger of a facility owner into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes a change of ownership. Transfer of corporate stock (even when a controlling interest), or the merger of another corporation into the originally-licensed corporation does not constitute a change of ownership.

3. Leasing. The lease of a facility's operations constitutes a change of ownership. Sale/lease -back agreements shall not be treated as changes of ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

4. Transfers. Transfer of a facility's legal title, or a transfer between levels of government constitutes a change of ownership. A transfer between departments of the same level of government does not constitute a change of ownership.

5. 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.

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.

1200-8-35-.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.

(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.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, and 68-11-216.

1200-8-35-.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 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 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.

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

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

1200-8-35-.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 0880-2-.16; or

(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 0880-2-.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.

1200-8-35-.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.

(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.

(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.

(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.

(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.

(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.

(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) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.

(f) 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;

(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.

1200-8-35-.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.

1200-8-35-.08 Building Standards.

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

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

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

shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.

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

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

(6) Review of plans and specifications shall be acknowledged in writing with copies sent to the architect and the owner, manager or other executive of the institution. The distribution of such review may be modified at the discretion of the department.

(7) All construction shall be executed in accordance with the approved plans and specifications.

(8) All new construction and renovations to outpatient diagnostic centers, other than minor alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in outpatient diagnostic centers, including the submission of phased construction plans and the final drawings and the specifications to each.

(9) In the event submitted materials do not appear to satisfactorily comply with 1200-8-35-.08 (4) the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(10) Notice of satisfactory review from the department constitutes compliance with this requirement if construction begins within one hundred eighty (180) days of the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any

restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

(11) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes.

(12) Prior to final inspection, a CD Rom disc, in TIF or DMG format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.

(13) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. These plans shall be prepared by an architect or engineer licensed to practice in the State of Tennessee. The plans shall contain a certificate signed by the architect or engineer that to the best of his or her knowledge or belief the plans conform to all applicable codes.

(a) Two (2) sets of plans shall be forwarded to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.

(b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.

(14) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies should be bound in an 8½ x 11 inch folder.

(15) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical, Electrical and Sprinkler.

(16) Architectural drawings shall include:

(a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;

(b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

(c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units. All fire and smoke walls must be identified;

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

(i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel must be indicated for elevators; and

(j) Code analysis.

(17) Structural drawings shall include:

(a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members;

(b) Schedules of beams, girders and columns; and

(c) Design live load values for wind, roof, floor, stairs, guard, handrails, and seismic.

(18) Mechanical drawings shall include:

(a) Specifications which show the complete heating, ventilating, fire protection, medical gas systems and air conditioning systems;

(b) Water supply, sewerage and HVAC piping systems;

(c) Pressure relationships shall be shown on all floor plans;

(d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;

(e) Water supply, sewage and drainage with all lines, risers, catch basins, manholes and cleanouts clearly indicated as to location, size, capacities, etc., and location and dimensions of septic tank and disposal field; and,

(f) Color coding to show clearly supply, return and exhaust systems.

(19) Electrical drawings shall include:

(a) A certification that all electrical work and equipment is in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;

(b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building;

(c) The electrical system shall comply with applicable codes, and shall include:

1. The fire alarm system; and

2. The emergency power system including automatic services as defined by the codes.

(d) Color coding to show all items on emergency power.

(20) Sprinkler drawings shall include:

(a) Shop drawings, hydraulic calculations, and manufacturer cut sheets;

(b) Site plan showing elevation of fire hydrant to building, test hydrant, and flow data (Data from within a 12 month period); and

(c) Show "Point of Service" where water is used exclusively for fire protection purposes.

(21) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.

(a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.

(b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.

(c) Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at shower, bathing and hand washing facilities shall be between 105°F.and 115°F.

(22) The following alarms are required and shall be monitored twenty-four (24) hours per day:

(a) Fire alarms; and

(b) Generators (if applicable)

(23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.

(24) With the submission of plans the facility shall specify the evacuation capabilities of the patients as defined in the National Fire Protection Code (NFPA). This declaration will determine the design and construction requirements of the facility.

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.

1200-8-35-.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.

1200-8-35-.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;

(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. 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.

1200-8-35-.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) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

    (i) procedure related injury requiring repair or removal of an organ;

    (ii) hemorrhage;

    (iii) displacement, migration or breakage of an implant, device, graft or drain;

    (iv) post operative wound infection following clean or clean/contaminated case;

    (v) any unexpected operation or reoperation related to the primary procedure;

    (vi) hysterectomy in a pregnant woman;

    (vii) ruptured uterus;

    (viii) circumcision;

    (ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

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

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are

reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in

any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for

broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(5) 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.

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

Authority: T.C.A. §§4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, and 68-11-216.

1200-8-35-.12 Patient Rights.

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

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

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

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

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

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

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

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

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

1200-8-35-.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 advance directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(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

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 1200-8-35-.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 1200-8-35-.13(16)(c) thru 1200-8-35-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

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

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

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

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

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

(l) Except as provided in 1200-8-35-.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.

(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 1200-8-35-.13(20) thru 1200-8-35-.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 1200-8-35-.13(20) thru 1200-8-35-.13(22) shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) A universal do not resuscitate order (DNR) may be issued by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:

1. with the consent of the patient; or

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

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

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

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

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

(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure

that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.

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

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

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1803, 68-11-1804, 68-11-1806 through 68-11-1810, 68-11-1813, and 68-11-1814.

1200-8-35-.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:

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.

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 26th day of October, 2005 and will become effective on the 9th day of January, 2006.