CHAPTER 0720-47
STANDARDS FOR UNITS OF MAJOR MEDICAL EQUIPMENT

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0720-47-.01 DEFINITIONS.

(1) "Abuse". Means willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of Abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal Abuse, sexual Abuse, physical Abuse, and mental Abuse including Abuse facilitated or enabled through the use of technology.

(2) Acceptable Plan of Correction. The Licensing Division approves a Licensee of any Unit of Major Medical Equipment'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; and

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

(3) Accredited. The process of verifying compliance with operational standards by a federally recognized accrediting body.

(4) American College of Radiology (ACR). The American College of Radiology.

(5) Accredited Record Technician (ART). A Person currently Accredited as such by the American Medical Records Association.

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

(7) Agent. An individual designated in an Advance Directive for Health Care to make a Health Care Decision for the individual granting the power.

(8) 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.

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

(10) 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.

(11) 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.

(12) 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.

(13) 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.

(14) Collaborative Plan. The formal written plan between the Mid-Level Practitioners and licensed Physician.

(15) 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.

(16) Commission. The Tennessee Health Facilities Commission.

(17) Competent. A Patient who has Capacity.

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

(19) 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.

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

(21) Designated Physician. A Physician designated by an individual or the individual's Agent, Guardian, or Surrogate, to have primary responsibility for the individual's Health Care or, in the absence of a designation or if the Designated Physician is not Reasonably Available, a Physician who undertakes such responsibility.

(22) Do-Not-Resuscitate Order (DNR). A written order, other than a POST, not to resuscitate a Patient in cardiac or respiratory arrest in accordance with accepted medical practices.

(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 0720-47-.10 or T.C.A. § 52-3-212, 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. Either a certified nurse practitioner or a physician assistant.

(48) Misappropriation of Patient/Resident Property. The deliberate misplacement, exploitation or wrongful, temporary or permanent use of an individual's belongings or money without the individual's consent.

(49) Neglect. The failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness; however, the withholding of authorization for or provision of medical care to any terminally ill Person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of the living will, shall not be deemed "Neglect" for purposes of these rules.

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

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

(52) 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.

(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, T.C.A. Chapters 6 or 9.

(57) Physician Assistant. A Person who has graduated from a Physician Assistant educational program Accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a Physician Assistant under T.C.A., Chapter 19.

(58) Physician Orders for Scope of Treatment or POST. Written orders that:

(a) Are on a form approved by the Commission:

(b) Apply regardless of the treatment setting and that are signed as required herein by the Patient's Physician, Physician Assistant, nurse practitioner, or clinical nurse specialist; and

(c) Specify:

1. Whether, in the event the Patient suffers cardiac or respiratory arrest, Cardiopulmonary Resuscitation should or should not be attempted; and

2. Other medical interventions that are to be provided or withheld, if any.

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

(60) Power of Attorney for Health Care. The designation of an Agent to make Health Care Decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(61) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other Emergency Responders.

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

(63) 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.

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

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

(66) Shall or Must. Compliance is mandatory.

(67) 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.

(68) 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, e.g. tumor.

(69) 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.

(70) Surrogate. An individual, other than a Patient's Agent or Guardian, authorized to make a Health Care Decision for the Patient.

(71) 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.

(72) Treating Health Care Provider. A Health Care Provider who at the time is directly or indirectly involved in providing Health Care to the Patient.

(73) Unit of Major Medical Equipment. Means any stationary or mobile unit of the following equipment:

(a) Magnetic Resonance Imaging (MRI) machines; or

(b) Positron Emission Tomography (PET) machines.

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

Authority: *T.C.A. §§ 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-216, 68-11-224, and 68-11-1802.*

0720-47-.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 Unit of Major Medical Equipment, as defined, without having a license. A license shall be issued only to the Person or Persons named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be posted conspicuously in the vicinity of any Unit of Major Medical Equipment.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Commission.

(b) Each applicant for a license shall pay an annual license fee in the amount of five hundred dollars ($500.00) per any Unit of Major Medical Equipment. The fee must be submitted with the initial application or renewal application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Commission. Major medical equipment shall not be used on Patients until a license has been issued. Applicants shall not hold themselves out to the public as being able to provide major medical equipment services until the license has been issued. A license shall not be issued until the Unit of Major Medical Equipment is in substantial compliance with these rules and regulations including submission of all information required by T.C.A. § 68-11-206(a)(1), or as later amended, and all information required by the Commission.

(d) The applicant must prove the ability to meet the financial needs to operate any Unit of Major Medical Equipment.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the location of, as well as any unit of, major medical equipment to be inspected by a Commission surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Commission that must be accepted by the Commission. Once the deficiencies have been corrected, then the Commission shall consider the application for licensure.

(3) Each Unit of Major Medical Equipment, when issued a license, shall be classified according to the type of services rendered. The Unit of Major Medical Equipment shall confine its services only 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 Commission a minimum of thirty (30) calendar days prior to the change. A new application and fee must be received by the Commission before the license may be issued.

(a) For the purposes of licensing, the Licensee of any Unit of Major Medical Equipment has the ultimate responsibility for the operation of said equipment, 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 any Unit of Major Medical Equipment is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which any Unit of Major Medical Equipment is owned and operated and any ownership interest of the preceding or succeeding entity changes.

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

1. Transfer of any Unit of Major Medical Equipment's legal title;

2. Lease of the Unit of Major Medical Equipment's operation;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the Unit of Major Medical Equipment;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Merger of a Unit of Major Medical Equipment's owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

6. The consolidation of a corporate owner with one or more corporations;

7. Transfers between levels of government; or

8. Temporary management where ultimate authority and operational control is surrendered and transferred from the owner to a new manager.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government;

5. Corporate stock transfers or sales, even when a controlling interest;

6. For a member-managed or manager-managed Limited Liability Company (LLC), an equity transfer or sale, even when a controlling interest; or

7. Management agreements where the owner continues to retain ultimate authority for the operation of any Unit of Major Medical Equipment.

(e) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves any Unit of Major Medical Equipment's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner.

(f) MRI and PET Unit requirements:

1. A Person who provides MRI services, the following licensing requirements apply to each unit:

(i) Must become Accredited within two years of licensure per machine and per diagnostic type; and

(ii) Must adhere to all federal and state regulations.

2. For Pediatric MRI Units, a Person who initiates Magnetic Resonance Imaging services shall notify the Commission in writing that imaging services are being initiated and shall indicate whether Magnetic Resonance Imaging services will be provided to a Patient who is fourteen (14) years of age or younger on more than five (5) occasions per year

3. A Person who provides PET services, the following licensing requirements apply:

   (i) Each PET unit must become Accredited within two years of licensure per machine and per diagnostic type.

   (ii) Must adhere to all federal and state regulations. All units must also adhere to the Nuclear Regulatory Commission requirements.

4. A Person who provides MRI services and/or PET services shall file with the Commission an annual report no later than thirty (30) days following the end of each state fiscal year that details the mix of payers by percentage of cases for the prior calendar year for its Patients, including private pay, private insurance, uncompensated care, charity care, Medicare, and Medicaid.

(5) Renewal.

(a) In order to renew a license, each Person offering major medical equipment services shall submit to periodic inspections by Commission surveyors for compliance with these rules. If deficiencies are noted, the Licensee shall submit an Acceptable Plan of Correction and shall remedy the deficiencies. In addition, each Licensee shall submit a renewal form approved by the Commission and applicable renewal fee prior to the expiration date of the license.

(b) If a Licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) calendar days thereafter, the Licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a Licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the Licensee shall reapply for a license by submitting the following to the Commission:

1. A completed application for licensure;

2. The license fee provided in rule 0720-47-.02(2)(b); and

3. Any other information required by the Commission.

(d) Upon reapplication, the Licensee shall submit to an inspection of any major medical equipment by Commission surveyors.

Authority: *T.C.A. §§ 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, and 68-11-216.*

0720-47-.03 DISCIPLINARY PROCEDURES.

(1) The Commission 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;

~~(b)~~(c) Violation of the Accreditation Standards following the initial accreditation period;

~~(c)~~(d) Permitting, aiding or abetting the commission of any illegal act in the operation of any Unit of Major Medical Equipment;

~~(d)~~(e) Conduct or practice found by the Commission to be detrimental to the health, safety, or welfare of the Patients receiving services from any Unit of Major Medical Equipment; and

~~(e)~~(f) Failure to renew license.

(2) The Commission 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;

(c) The conduct of the Licensee in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the Licensee of statutes, regulations or orders of the Commission.

(3) When any Unit of Major Medical Equipment is found by the Commission to be in violation of this chapter, the Commission will issue a statement of deficiencies to the Licensee. Within ten (10) calendar 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 Commission that the plan of correction is unacceptable shall subject Unit of Major Medical Equipment's license to possible disciplinary action.

(5) Any Licensee or applicant for a license, aggrieved by a decision or action of the Commission, pursuant to this chapter, may request a hearing before the Commission. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §§ 4-5-101 et seq.

(6) Reconsideration and Stays. The Commission authorizes the member who chaired the Commission for a contested case to be the Commission member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.

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Authority: *T.C.A. §§ 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-208, 68-11-209, and 68-11-216.*

0720-47-.04 ADMINISTRATION.

(1) Each Unit of Major Medical Equipment must have an effective governing body legally responsible for the conduct and use of said equipment. If any Unit of Major Medical Equipment does not have an organized governing body, the Persons legally responsible for the conduct and use of any Unit of Major Medical Equipment 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 either each individual Unit of Major Medical Equipment or all units licensed by the Licensee. 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 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 owner-operator alone or that of a parent organization, shall establish effective mechanisms to ensure the accountability of the Medical Staff and other professional personnel operating and overseeing each Unit of Major Medical Equipment.

(5) The governing body or individual responsible shall assure that each Unit of Major Medical Equipment has the financial resources to provide the services essential to its operation.

(6) Staffing shall correspond withal staffing requirements outlined by the accrediting body that each Unit of Major Medical Equipment is either Accredited by or is in the process of seeking accreditation from, including staff education and training programs.

(7) Staff operating or overseeing each Unit of Major Medical Equipment shall assess and provide adequate comfort measures as needed.

(8) Each Unit of Major Medical Equipment shall perform only those procedures which can be safely and effectively carried out.

(9) Each Licensee of any Unit of Major Medical Equipment must establish written policies and procedures that assure that all procedures performed are medically necessary and will not unnecessarily duplicate other services.

(10) Each Licensee of any Unit of Major Medical Equipment must establish written policies and procedures for how emergencies within the MRI unit facility will be managed and documented in conformity with accepted medical practice and all relevant state and federal law.

(11) Each Licensee of any Unit of Major Medical Equipment must demonstrate that the proposed procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies requirements.

(12) The Food and Drug Administration (FDA) must certify any MRI or PET unit for clinical use prior to use.

(13) Each Unit of Major Medical Equipment shall have at all times a licensed Physician who shall

be responsible for the direction and coordination of procedures.

(14) 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.

(15) 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.

(16) Whenever the rules and regulations of this chapter require that a Licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the Licensee shall develop the required policy, maintain it and adhere to its provisions. A Licensee of any Unit of Major Medical Equipment which violates a required policy also violates the rule and regulation establishing the requirement.

(17) Policies and procedures shall be consistent with professionally recognized standards of practice.

(18) No Licensee of any Unit of Major Medical Equipment shall retaliate against or, in any manner, discriminate against any Person because of a complaint made in good faith and without malice to the Commission, Adult Protective Services, or the Comptroller of the State Treasury. A Licensee of any Unit of Major Medical Equipment 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.

(19) 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.

(20) 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.

(21) 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.

(22) All Health Care facilities licensed pursuant to T.C.A. § 68-11-201 shall post the following in the main public entrance:

(a) 1. Contact information including statewide toll-free number of the division of Adult Protective Services, and the number for the local district attorney's office;

2. A statement that a Person of advanced age who may be the victim of Abuse, Neglect, or exploitation may seek assistance or file a complaint with the division concerning Abuse, Neglect and exploitation; and

3. A statement that any Person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

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

(23) "No smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.

Authority: *T.C.A. §§ 39-17-1803, 39-17-1805, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268, and 71-6-121.*

0720-47-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) All procedures provided by a Unit of Major Medical Equipment 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 by a Unit of Major Medical Equipment may be ordered by the following:

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

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

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

(3) The Licensee 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 any Unit of Major Medical Equipment. The Licensee of any Unit of Major Medical Equipment 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 rules pertaining to any Unit of Major Medical Equipment.

(5) The Licensee of any Unit of Major Medical Equipment 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. §§ 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.*

0720-47-.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 dosimeter 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. Readings should be below the Nuclear Regulatory Commission (NRC) acceptable levels. As low as reasonably achievable (ALARA) is required for levels above the acceptable limit.

(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 all units of major medical 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 related to operation of any Unit of Major Medical Equipment including the equipment itself.

(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 Licensee of each Unit of Major Medical Equipment requiring radiopharmaceuticals shall maintain records of the receipt and disposition of said radiopharmaceuticals.

(2) Invasive Procedures.

(a) If the Licensee of any Unit of Major Medical Equipment provides invasive diagnostic procedures e.g. Cardiac Catheterization, Percutaneous Transluminal Coronary Angioplasty, vascular embolization or Stereotactic Procedures using anesthesia, the services must be well organized and provided in accordance with acceptable standards of practice.

(b) A qualified Registered Nurse shall be present during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.

(c) Properly executed informed consent forms shall be in the Patient's chart before procedure is performed, except in emergencies.

(d) Adequate equipment and supplies shall be available to the invasive diagnostic room

and to the post procedure care area**.** The following equipment and supplies shall be provided for Cardiac Catheterization or angioplasty:

1. Call-in system;

2. Cardiac monitor;

3. Pulse Oximeter;

4. Resuscitator;

5. Defibrillator;

6. Aspirator; and

7. Tracheotomy set.

(e) A crash cart must be available with appropriate medications.

(f) A qualified Registered Nurse shall be in the post procedure area during the Patient's recovery period during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.

(g) A report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following the procedure and signed by the Physician.

(h) The Licensee of any Unit of Major Medical Equipment providing invasive procedures 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 for any major medical unit procedure.

(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 Licensee 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 Licensee of any Unit of Major Medical Equipment 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 Licensee of any Unit of Major Medical Equipment shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.

(b) The Licensee of any Unit of Major Medical Equipment 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 Licensee of any Unit of Major Medical Equipment 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 any Unit of Major Medical Equipment 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 the Commission.

~~(7) Infection Control.~~

~~(a) The Licensee of any item of major medical equipment 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 Licensee of any Unit of Major Medical Equipment 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 Licensee, a student studying at the location of any Unit of Major Medical Equipment, or other Health Care Provider rendering services for the Licensee of any Unit of Major Medical Equipment 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 Licensee of any Unit of Major Medical Equipment and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.~~

~~(d) All Licensee of any Unit of Major Medical Equipment 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) A Licensee of any Unit of Major Medical Equipment shall have an annual influenza vaccination program which shall include at least:~~

~~1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the Person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Licensee of any Unit of Major Medical Equipment will encourage all staff and independent practitioners to obtain an influenza vaccination;~~

~~2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at http://tennessee.gov/health/topic/hcf-provider);~~

~~3. Education of all employees about the following:~~

~~(i) Flu vaccination,~~

~~(ii) Non-vaccine control measures, and~~

~~(iii) The diagnosis, transmission, and potential impact of influenza;~~

~~4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and~~

~~5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the Licensee in the event of a vaccine shortage as declared by the Commission.~~

~~(f) The physical environment of the Licensee of any major unit of medical equipment shall be maintained in a safe, clean and sanitary manner.~~

~~(g) Any condition on the 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)~~(7) Performance Improvement. The Licensee of any Unit of Major Medical Equipment 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; and

(e) Documentation that the above policies are being followed and that appropriate action is taken whenever indicated.

~~(9)~~(8) 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)~~(9) Laboratory Services.

(a) The Licensee of any Unit of Major Medical Equipment 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 provided by any Unit of Major Medical Equipment.

~~(11)~~(10) Food and Dietetic Services. If a Patient will be in the Licensee's care for more than four (4) hours post- op, an appropriate diet shall be provided.

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

0720-47-.07 BUILDING STANDARDS.

(1) A Licensee of any Unit of Major Medical Equipment shall construct, arrange, maintain, and/or ensure the condition of the physical location of the unit(s) of major medical equipment and the overall environment in such a manner that the safety and well-being of the Patients are assured, and all units of major medical equipment are housed, moved, maintained, and operated in accordance with all state and federal regulations

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

0720-47-.08 LIFE SAFETY.

(1) The Licensee of any Unit of Major Medical Equipment which complies with the required applicable building and fire safety regulations at the time the Commission 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 Licensee of any Unit of Major Medical Equipment shall provide fire protection by the elimination of fire hazards, by the installation of necessary firefighting 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 Commission within seven (7) calendar 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 Licensee may omit the name(s) of Patient(s) and parties involved, however, should the Commission find the identities of such Persons to be necessary to an investigation, the Licensee shall provide such information.

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

0720-47-.09 RECORDS AND REPORTS.

(1) The Licensee of any Unit of Major Medical Equipment shall report information contained in the Medical Records of Patients who have cancer, pre-cancerous, or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the Tennessee Department of Health on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(2) The Licensee of any Unit of Major Medical Equipment shall report to the Tennessee Department of Health each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of the licenses for any Unit of Major Medical Equipment under license.

(3) The Licensee of any Unit of Major Medical Equipment center shall report all incidents of Abuse, Neglect, and misappropriation to the Commission in accordance with T.C.A. § 68-11-211.

(4) The Licensee of any Unit of Major Medical Equipment shall report the following incidents to the Commission in accordance with T.C.A. § 68-11-211.

(a) Strike by staff;

(b) External disasters impacting any Unit of Major Medical Equipment;

(c) Disruption of any service vital to the continued safe operation of any Unit of Major Medical Equipment or to the health and safety of its Patients and personnel; and

(d) Fires that disrupt the provision of Patient care services or cause harm to the Patients or staff, or that are reported by the Licensee of any Unit of Major Medical Equipment to any entity, including but not limited to a fire department charged with preventing fires.

(5) Legible copies of the following records and reports shall be retained by the Licensee of any Unit of Major Medical Equipment, 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) Commission licensure and fire safety inspections and surveys;

(e) Commission 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 Executive Director or Commission, 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. §§ 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, and 68-11-216.*

0720-47-.10 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 Licensee of any Unit of Major Medical Equipment must notify the Commission 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 Licensee of any Unit of Major Medical Equipment 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. §§ 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.*

0720-47-.11 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each Licensee of any Unit of Major Medical Equipment 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 Licensee of any Unit of Major Medical Equipment may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Commission.

(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) The Licensee of any Unit of Major Medical Equipment 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 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 Licensee of any Unit of Major Medical Equipment is providing services to the Patient.

(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 0720-47-.11(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 0720-47-.11(16)(c) through 0720-47-.11(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 Licensee of any Unit of Major Medical Equipment's ethics mechanism or standing committee in the facility at which the unit is located 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 0720-47-.11(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 0720-47-.11(20) through 0720-47-.11(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 or Licensee of any Unit of Major Medical Equipment 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 or Licensee of any Unit of Major Medical Equipment 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 0720-47-.11(20) through 0720-47-.11(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 effectuated, or until the determination has been made that Transfer cannot be effectuated;

(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 effectuated, 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) Physician Orders for Scope of Treatment (POST), if applicable:

(a) Physician Orders for Scope of Treatment (POST) may be issued by a physician for a Patient with whom the Physician has a bona fide Physician-Patient relationship, but only:

1. With the informed consent of the Patient;

2. If the Patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon request of and with the consent of the Agent, Surrogate, or other Person authorized to consent on the Patient's behalf under the Tennessee Health Care Decisions Act; or

3. If the Patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the Agent, Surrogate, or other Person authorized to consent on the Patient's behalf under the Tennessee Health Care Decisions Act, is not Reasonably Available, if the Physician determines that the provision of Cardiopulmonary Resuscitation would be contrary to accepted medical standards.

(b) A POST may be issued by a Physician Assistant, nurse practitioner or clinical nurse specialist for a Patient with whom such Physician Assistant, nurse practitioner or clinical nurse specialist has a bona fide Physician Assistant-Patient or nurse-Patient relationship, but only if:

1. No Physician, who has a bona fide Physician-Patient relationship with the Patient, is present and available for discussion with the Patient (or if the Patient is a minor or is otherwise incapable of making an informed decision, with the Agent, Surrogate, or other Person authorized to consent on the Patient's behalf under the Tennessee Health Care Decisions Act);

2. Such authority to issue is contained in the Physician Assistant's, nurse practitioner's, or clinical nurse specialist's protocols;

3. Either:

(i) The Patient is a resident of a nursing home licensed under title 68 or an ICF/MR facility licensed under title 33 and is in the process of being discharged from the nursing home or Transferred to another facility at the time the POST is being issued; or

(ii) The Patient is a hospital Patient and is in the process of being discharged from the hospital or Transferred to another facility at the time the POST is being issued; and

4. Either:

(i) With the informed consent of the Patient;

(ii) If the Patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon request of and with the consent of the Agent, Surrogate, or other Person authorized to consent on the Patient's behalf under the Tennessee Health Care Decisions Act; or

(iii) If the Patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the Agent, Surrogate, or other Person authorized to consent on the Patient's behalf under the Tennessee Health Care Decisions Act, is not Reasonably Available and such authority to issue is contained in the Physician Assistant, nurse practitioner or clinical nurse specialist's protocols and the Physician Assistant or nurse determines that the provision of Cardiopulmonary Resuscitation would be contrary to accepted medical standards.

(c) If the Patient is an Adult who is capable of making an informed decision, the Patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke any contrary order in the POST. If the Patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the Patient be resuscitated by the Person authorized to consent on the Patient's behalf shall revoke any contrary order in the POST. Nothing in this section shall be construed to require Cardiopulmonary Resuscitation of a Patient for whom the Physician or Physician Assistant or nurse practitioner or clinical nurse specialist determines Cardiopulmonary Resuscitation is not medically appropriate.

(d) A POST issued in accordance with this section shall remain valid and in effect until revoked. In accordance with this rule and applicable regulations, qualified emergency medical services personnel; and licensed Health Care practitioners in any facility, program, or organization operated or licensed by the Commission, the Department of Mental Health and Substance Abuse Services, or the Department of Disability and Aging, or operated, licensed, or owned by another state agency, shall follow a POST that is available to such Persons in a form approved by the Commission.

(e) Nothing in these rules shall authorize the withholding of other medical interventions, such as medications, positioning, wound care, oxygen, suction, treatment of airway obstruction or other therapies deemed necessary to provide comfort care or alleviate pain.

(f) If a Person has a Do-Not-Resuscitate Order in effect at the time of such Person's discharge from a Health Care facility, the facility shall complete a POST prior to discharge. If a Person with a POST is Transferred from one Health Care facility to another Health Care facility, the Health Care facility initiating the Transfer shall

communicate the existence of the POST to Qualified Emergency Medical Service Personnel and to the receiving facility prior to the Transfer. The Transferring facility shall provide a copy of the POST that accompanies the Patient in transport to the receiving Health Care facility. Upon admission, the receiving facility shall make the POST a part of the Patient's record.

(g) These rules shall not prevent, prohibit, or limit a Physician from using a written order, other than a POST, not to resuscitate a Patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices. This action shall have no application to any do not resuscitate order that is not a POST, as defined in these rules.

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

Authority: *T.C.A. §§ 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1803, 68-11-1804, 68-11-1805, 68-11-1806 through 68-11-1810, 68-11-1813, and 68-11-1814.*

720-47-.12 APPENDIX I

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

Tennessee Physician Orders for Scope of Treatment (POST, sometimes called "POLST") This is a Physician Order Sheet based on the medical conditions and wishes of the person identified at right ("patient"). Any section not completed indicates full treatment for that section. When need occurs, first follow these orders, then contact physician.	Patient's Last Name First Name/Middle Initial Date of Birth

Section A *Check One Box Only*	**CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse and is not breathing.** ☐ **Resuscitate(CPR)** ☐ **Do Not Attempt Resuscitation (DNR / no CPR) (Allow Natural Death)** When not in cardiopulmonary arrest, follow orders in **B, C,** and **D.**
Section B *Check One Box Only*	**MEDICAL INTERVENTIONS. Patient has pulse and/or is breathing.** ☐ **Comfort Measures Only.** Relieve pain and suffering through the use of any medication by any route, positioning, wound care and other measures. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. **Do not transfer to hospital for life-sustaining treatment. Transfer only if comfort needs cannot be met in current location. Treatment Plan: Maximize comfort through symptom management.** ☐ **Limited Additional Interventions.** In addition to care described in Comfort Measures Only above, use medical treatment, antibiotics, IV fluids and cardiac monitoring as indicated. No intubation, advanced airway interventions, or mechanical ventilation. May consider less invasive airway support (e.g. CPAP, BiPAP). **Transfer** to hospital if indicated. Generally avoid the intensive care unit. **Treatment Plan: basic medical treatments.** ☐ **Full Treatment.** In addition to care described in Comfort Measures Only and Limited Additional Interventions above, use intubation, advanced airway interventions, and mechanical ventilation as indicated. **Transfer** to hospital and/or intensive care unit if indicated. **Treatment Plan: Full treatment including in the intensive care unit.** *Other Instructions:*_____

Section C *Check One*	**ARTIFICIALLY ADMINISTERED NUTRITION. Oral fluids & nutrition must be offered if feasible.** ☐ No artificial nutrition by tube. ☐ Defined trial period of artificial nutrition by tube. ☐ Long-term artificial nutrition by tube. *Other Instructions:* _____

Section D *Must be Completed*	**Discussed with:** ☐ Patient/Resident ☐ Health Care Agent ☐ Court-appointed guardian ☐ Health Care Surrogate ☐ Parent of minor ☐ Other: _____(Specify)	**The Basis for These Orders Is:** (Must be completed) ☐ Patient's preferences ☐ Patient's best interest (patient lacks capacity or preferences unknown) ☐ Medical indications ☐ (Other) _____

Physician/NP/CNS/PA Name (Print)	**Physician/NP/CNS/PA Signature** **Date** NP/CNS/PA (Signature at Discharge)	**MD/NP/CNS/PA** **Phone Number:**

Signature of Patient, Parent of Minor, or Guardian/Health Care Representative

Preferences have been expressed to a physician and/or Health Care professional. It can be reviewed and updated at any time if your preferences change. If you are unable to make your own Health Care decisions, the orders should reflect your preferences as best understood by your Surrogate.

Name (print)	Signature	Relationship (write "self" if patient)

Agent/Surrogate	Relationship	Phone Number

Health Care Professional Preparing Form	Preparer Title	Phone Number	Date Prepared

Directions for Health Care Professionals

Completing POST

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

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

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

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

Using POST

Any incomplete section of POST implies full treatment for that section.

No defibrillator (including AEDs) should be used on a person who has chosen "Do Not Attempt Resuscitation". Oral

fluids and nutrition must always be offered if medically feasible.

When comfort cannot be achieved in the current setting, the person, including someone with "Comfort Measures Only", should be transferred to a setting able to provide comfort (e.g., treatment of a hip fracture).

IV medication to enhance comfort may be appropriate for a person who has chosen "Comfort Measures Only".

Treatment of dehydration is a measure which prolongs life. A person who desires IV fluids should indicate "Limited Interventions" or "Full Treatment".

A person with capacity, or the Health Care Agent or Surrogate of a person without capacity, can request alternative treatment.

Reviewing POST

This POST should be reviewed if:

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

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

(2) Advance Directive for Health Care Form.

ADVANCE DIRECTIVE FOR HEALTH CARE*
(Tennessee)

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

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

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

Name: _____ Relation: _____Home Phone: _____Work Phone: _____
Address: _____Mobile Phone: _____Other Phone:

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

Name: _____ Relation: _____Home Phone: _____Work Phone:
Address: _____Mobile Phone: _____Other Phone:

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

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

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

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

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

☐ Yes	☐ No	**CPR (Cardiopulmonary Resuscitation):** To make the heart beat again and restore breathing after it has stopped. Usually this involves electric shock, chest compressions, and breathing assistance.

☐ Yes	☐ No	**Life Support / Other Artificial Support:** Continuous use of breathing machine, IV fluids, medications, and other equipment that helps the lungs, heart, kidneys, and other organs to continue to work.
☐ Yes	☐ No	**Treatment of New Conditions:** Use of surgery, blood transfusions, or antibiotics that will deal with a new condition but will not help the main illness.
☐ Yes	☐ No	**Tube feeding/IV fluids:** Use of tubes to deliver food and water to a patient's stomach or use of IV fluids into a vein, which would include artificially delivered nutrition and hydration.

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

(Attach additional pages if necessary)

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

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

☐ No organ/tissue donation

SIGNATURE

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

Signature: _____ Date: _____
(Patient)

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

Witnesses:

1. I am a competent Adult who is not named as the Agent or alternate. I witnessed the patient's signature on this form. _____
Signature of witness number 1

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

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

STATE OF TENNESSEE

COUNTY OF _____

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

My commission expires: _____ _____
Signature of Notary Public

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

* This form replaces the old forms for durable Power of Attorney for Health Care, living will, appointment of Agent, and advance care plan, and eliminates the need for any of those documents.

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