**From:** Holly Vickers
**To:** Scott Faragher
**Subject:** FW: NICU TAG - Rule Feedback requested
**Date:** Tuesday, June 17, 2025 2:44:33 PM
**Attachments:** image002.png

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**From:** Lisa McClane <Lisa.McClane@lebonheur.org>
**Sent:** Wednesday, April 30, 2025 5:23 PM
**To:** Holly Vickers <Holly.Vickers@tn.gov>; Rolli, Alice G <alice.rolli@tnchat.org>
**Cc:** Sara Burnett <Sara.Burnett@lebonheur.org>; Katie Thomas <Katie.Thomas@tn.gov>
**Subject:** [EXTERNAL] RE: NICU TAG - Rule Feedback requested



*I just realized I said 24-28 hours below; I meant 24-48 hours!*

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**From:** Lisa McClane
**Sent:** Wednesday, April 30, 2025 2:35 PM
**To:** Holly Vickers <Holly.Vickers@tn.gov>; Rolli, Alice G <alice.rolli@tnchat.org>
**Cc:** Sara Burnett <Sara.Burnett@lebonheur.org>; Katie Thomas <Katie.Thomas@tn.gov>
**Subject:** RE: NICU TAG - Rule Feedback requested

*OK, here are my comments on the document.*
*As to the definition of Special Care Nursery, in my opinion, there is no difference between a level II nursery and a special care nursery. This guideline did not cover requirements for a level I nursery, although I think that would be a good thing to do. A level I nursery should be able to provide for any minor illness in an otherwise normal term newborn, such as phototherapy, glucose or antibiotic infusions and non-invasive short-term oxygen therapy. Any treatment more extensive than that should be carried out in a level II or higher nursery.*
*I provided some feedback on the level II vs level III care on page 64; in general, I do not think a neonate meeting level III requirements should be treated at a level II nursery, regardless of medical director opinion. Staff in a level II nursery may not be adequately trained to recognize increasing severity of illness. I know here at Le Bonheur, we have received babies from hospitals who should have been transferred earlier with some experiencing poor outcomes as a result. The only exception I would make is if there are no higher level nursey beds available in the region and the infant is expected to substantially improve in 24-28 hours.*
*Have a great day!*
*Lisa*

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**From:** Holly Vickers <Holly.Vickers@tn.gov>
**Sent:** Wednesday, April 30, 2025 12:53 PM
**To:** Lisa McClane <Lisa.McClane@lebonheur.org>; Rolli, Alice G <alice.rolli@tnchat.org>
**Cc:** Sara Burnett <Sara.Burnett@lebonheur.org>; Katie Thomas <Katie.Thomas@tn.gov>
**Subject:** [EXTERNAL] RE: NICU TAG - Rule Feedback requested



Good afternoon,

You are correct. This group is different from the Tennessee Perinatal Guidelines subcommittee. While we operate more ad hoc, we plan to meet with the Technical Advisory Group (TAG) on an ongoing basis. The draft does represent most of the recommendations from the TAG; however, we're still gathering additional feedback to create a comprehensive set that may be incorporated into the rules.

-Holly

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**From:** Lisa McClane <Lisa.McClane@lebonheur.org>
**Sent:** Wednesday, April 30, 2025 11:22 AM
**To:** Holly Vickers <Holly.Vickers@tn.gov>; Rolli, Alice G <alice.rolli@tnchat.org>
**Cc:** Sara Burnett <Sara.Burnett@lebonheur.org>
**Subject:** [EXTERNAL] RE: NICU TAG - Rule Feedback requested

*Thank you both. I am thinking this group is a different incarnation of the Tennessee Perinatal Guidelines subcommittee that I used to sit on years ago, is that correct? Is this a group that meets routinely, or is it ad hoc when*

**RULES**
**OF**
**THE TENNESSEE HEALTH FACILITIES COMMISSION**

**CHAPTER 0720-14**
**STANDARDS FOR HOSPITALS**

**TABLE OF CONTENTS**



**0720-14-.01 DEFINITIONS.**

(1) AAP. Means American Academy of Pediatrics.

~~(1) Abuse. The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.~~

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

(a) How the deficiency will be corrected.

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

(c) The date the deficiency will be corrected.

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

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

(5) Acute Burn Care. The medical treatment of burn injuries during the initial weeks after the injury.

~~(3)~~(6) Adult. An individual who has capacity and is at least 18 years of age.

~~(4)~~(7) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

~~(5)~~(8) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

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

(9) Burn. Medically defined as a painful injury to the skin or other tissue caused by heat, electricity, radiation, chemicals, or friction.

(10) Burn Unit. A burn unit must belong to a general hospital that is Joint Commission accredited, or American Burn Association (ABA) verified.

(11) Burn Unit Director. An appropriately licensed surgeon (MD or DO) with the following:

(a) Board certification by the American Board of Surgery or American Board of Plastic Surgery,

(b) Within the preceding five years, one of the following:

1. A one-year fellowship in burn treatment, or

2. Two years of experience treating acute burn injuries.

(c) Advanced Burn Life Support (ABLS) certification.

(12) Burn Nurse Leader. An appropriate licensed Registered Nurse with the following:

(a) A minimum of a baccalaureate degree in nursing,

(b) Two years of acute burn treatment experience, or a training program designed by the Burn Unit Director to ensure competency,

(c) Advanced Burn Life Support (ABLS) certification.

~~(7)~~(13) 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

~~(8)~~(14) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

~~(9)~~(15) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

~~(10)~~(16) Certified Nurse Practitioner. A person who is licensed as a registered nurse and has further been issued a certificate of fitness to prescribe and/or issue legend drugs by the Tennessee Board of Nursing.

~~(11)~~(17) 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)~~(18) Certified Respiratory Therapist. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

~~(13)~~(19) Certified Respiratory Therapy Technician. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

~~(14)~~(20) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

~~(15)~~(21) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians and mid-level practitioners.

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

(23) Commission. The Tennessee Health Facilities Commission.

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

~~(17)~~(24) Competent. A patient who has capacity.

~~(18) Critical Access Hospital. A hospital located in a rural area, certified by the Department as being a necessary provider of health care services to residents of the area, which makes available twenty-four (24) hour emergency care; is a designated provider in a rural health network; provides not more than twenty-five (25) acute care inpatient beds for providing inpatient care not to exceed an annual average of ninety-six (96) hours, and has a quality assessment and performance improvement program and procedures for utilization review. If swing-bed approval has been granted, all twenty-five (25) beds can be used interchangeably for acute or Skilled Nursing Facility (SNF/swing-bed) level of care services.~~

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

~~(19)~~(26) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

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

~~(21)~~(27) 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)~~(28) Designation. An official finding and recognition by the Commission that an acute care hospital meets Tennessee State Rural Health Care Plan requirements to be a Critical Access Hospital or Rural Emergency Hospital.

~~(23)~~(29) Dietitian. As used in the chapter, the term "dietitian" means:

(a) A person who is currently licensed by the Tennessee Board of Dietitian/Nutritionist Examiners as a dietitian/nutritionist; or

(b) An employee of a Tennessee hospital who is exempt from Tennessee licensure pursuant to T.C.A. § 63-25-104(b)(6) but holds the credential of Registered Dietitian (RD) or Registered Dietitian Nutritionist (RDN) from the Commission on Dietetic Registration.

~~(24)~~(30) 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.

(31) E. Means essential requirement.

~~(25)~~(32) 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.

~~(26)~~(33) 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.

~~(27)~~(34) 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.

(35) Executive Director. The Executive Director of the Tennessee Health Facilities Commission.

~~(28)~~(36) 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.

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

(38) Guidelines for Perinatal Care. An educational resource to aid clinicians in providing obstetric and gynecological care developed through the collaborative efforts of the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG).

~~(29)~~(39) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

~~(30)~~(40) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

~~(31)~~(41) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

~~(32)~~(42) 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 0720-14-.13 or T.C.A. § 33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

~~(33)~~(43) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

~~(34)~~(44) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

~~(35)~~(45) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more non-related persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment. All hospitals shall provide basic hospital functions and may provide optional services as delineated in these rules. A hospital shall be designated according to its classification and shall confine its services to those classifications described below.

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

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

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

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

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

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

6. An emergency department in accordance with Rule 0720-14-.07(5) of these standards and regulations.

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

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

(c) Chronic Disease Hospital. To be licensed as a chronic disease hospital, the institution shall be devoted exclusively to the diagnosis, treatment or care of persons needing medical, surgical or rehabilitative care for chronic or long-term illness, injury, or infirmity. The diagnosis, treatment or care shall be administered by or performed under the direction of persons currently licensed to practice the healing arts in the State of Tennessee. A chronic disease hospital shall meet the requirements for a general hospital except that obstetrical facilities are not required and, if the hospital provides no surgical services, an emergency department is not required.

(d) Orthopedic Hospital. To be licensed as an orthopedic hospital, the institution shall be devoted primarily to the diagnosis and treatment of orthopedic conditions. An orthopedic

hospital shall meet the requirements for a general hospital except that obstetrical services are not required and, if the hospital provides no surgical services, an emergency department is not required.

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

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

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

~~(36)~~(46) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such persons, and maternity care involving labor and delivery for any period of time.

~~(37)~~(47) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

~~(38)~~(48) Individual Instruction. An individual's direction concerning a health care decision for the individual.

~~(39)~~(49) 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.

~~(40)~~(50) Involuntary Transfer. The movement of a patient between hospitals, without the consent of the patient, the patient's legal guardian, next of kin or representative.

~~(41)~~(51) Justified Emergency. Includes, but is not limited to, the following events/occurrences:

(a) An influx of mass casualties;

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

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

~~(42)~~(52) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

~~(43)~~(53) Licensed Health Care Professional. Any health care professional currently licensed by the State of Tennessee to practice within the scope of a regulated profession, such as a nurse practitioner, dietitian, dentist, occupational therapist, pharmacist, physical therapist,

physician, physician assistant, podiatrist, psychologist, clinical social worker, speech language pathologist, and emergency service personnel.

~~(44)~~(54) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

~~(45)~~(55) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

~~(46)~~(56) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(57) 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.

~~(47)~~(58) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part, which includes labor when delivery is imminent, when there is inadequate time to effect safe transfer to another hospital prior to delivery, or when a transfer may pose a threat to the health and safety of the patient or the unborn child.

~~(48)~~(59) 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.

~~(49)~~(60) Medical Staff. An organized body composed of individuals appointed by the hospital governing board that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

~~(50)~~(61) 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.

~~(51)~~(62) Member of the Professional Medical Community. A professional employed by the hospital and on the premises at the time of a voluntary delivery.

~~(52)~~(63) Mid-Level Practitioner. Either a certified nurse practitioner or a physician assistant.

~~(53)~~(64) 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.

~~(54)~~(65) 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. N.F.P.A. The National Fire Protection Association.

(66) Neonatal Care Units.

(a) Level II. Level II nurseries provide specialty neonatal services. They provide care for stable or moderately ill infants born at >32 weeks gestation and weighing >1500 grams who have problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis. These units also resuscitate and stabilize preterm and/or ill infants before transfer to a facility at which newborn intensive care is provided. Level II nurseries provide mechanical ventilation for brief (<24 hrs) duration and continuous positive airway pressure, until the infant's condition improves, or the infant can be transferred to a higher-level facility (American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012). In addition, Level II units provide care for infants who are convalescing after intensive care.

(b) Level III. Level III nurseries provide care for infants who are born at <32 weeks of gestation or weigh <1500 grams at birth or have complex medical or surgical conditions, regardless of gestational age. Level III units have continuously available personnel and equipment to provide life support for as long as needed. They can provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily accessible on site or by prearranged consultative agreements (American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012).

(c) Level IV. Level IV units include the capabilities of Level III units with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants. Pediatric medical and pediatric surgical specialty consultants must be continuously available 24 hours a day, 7 days a week. Level IV facilities also must have the capability for surgical repair of complex conditions (e.g., congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation) (American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012).

(67) Neonatal Intensive Care Unit (NICU). Shall have the same definition as provided in T.C.A. § 68-59-102(6).

(68) Neonatal Intensive Care Unit (NICU) Director. Please refer to 0720-14-.07(17)(b)(i).

(69) Neonatal Intensive Care Unit (NICU) Nurse Manager. Please refer to 0720-14-.07(17)(b)(ii).

(70) Neonatal Resuscitation Program (NRP). Is an evidence-based approach for the immediate resuscitation care of a newborn at birth, which was developed by the American Academy of Pediatrics (AAP) and the American Heart Association (AHA). NRP covers neonatal resuscitation equipment, administering neonatal CPR, and other lifesaving measures.

~~(55)~~(71) N.F.P.A. The National Fire Protection Association.

~~(56)~~(72) Nuclear Medicine Technologist. A person currently registered as such by the National Association for Nuclear Medicine Technology.

~~(57)~~(73) 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.

~~(58)~~(74) Occupational Therapist. A person currently certified as such by the Tennessee Board

of Occupational and Physical Therapy Examiners.

~~(59)~~(75) Occupational Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

~~(60)~~(76) Optometrist. A person currently licensed as such by the Tennessee Board of Optometry.

~~(61)~~(77) 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.

(78) Perinatal Advisory Committee (PAC). The Perinatal Advisory Committee was established by statute and exists as a consultative body to advise the Tennessee Department of Health in administration and implementation of the perinatal regionalization system across Tennessee. The Committee is composed of individuals with expertise and a vested interested in the health [redacted] local hospitals, medical specialists in obstetrics and newborn conditions/private practice, family physicians, obstetrical and neonatal intensive care nurses, a medical school, and the general public. (TCA §§ 68-1-803-804)

~~(62)~~(79) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

~~(63)~~(80) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

~~(64)~~(81) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

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

~~(65)~~(83) Physical Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

~~(66)~~(84) Physical Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

~~(67)~~(85) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

~~(68)~~(86) Physician Assistant. A person who has graduated from a physician assistant educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a physician assistant under Title 63, Chapter 19.

~~(69)~~(87) Physician Orders for Scope of Treatment or POST. Written orders that:

~~(a) Are on a form approved by the Board for Licensing Health Care Facilities;~~

(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) 1. Specify whether, in the event the patient suffers cardiac or respiratory arrest,

cardiopulmonary resuscitation should or should not be attempted;

2. Specify other medical interventions that are to be provided or withheld; or

3. Specify both 1. and 2.

~~(70)~~(88) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

~~(71)~~(89) 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.

(90) Program Objectives Report (POR). Defines the goals and projected results of a program.

~~(72)~~(91) Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

~~(73)~~(92) 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.

~~(74)~~(93) Radiological Technologist. A person currently registered as such by the American Society of Radiological Technologists.

~~(75)~~(94) 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.

(95) 

~~(76)~~(96) Registered Health Information Administrator (RHIA). A person currently registered as such by the American Health Information Management Association.

~~(77)~~(97) Registered Health Information Technician (RHIT). A person currently accredited as such by the American Health Information Management Association.

~~(78)~~(98) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

~~(79)~~(99) Rural Area. A county classified by the federal Office of Management and Budget (OMB) as rural, all counties, excluding Davidson, Hamilton, Knox, and Shelby, currently defined as rural in Chapter 1200-20-11 of the Tennessee Comprehensive Rules and Regulations, or an area outside of a county or part of a county previously classified as rural by the OMB and reclassified by the OMB as a metropolitan statistical area as of June 6, 2003.

~~(80)~~(100) Rural Emergency Hospital. A Rural Emergency Hospital ("REH") is a facility that:

(a) Meets the eligibility requirements for a licensed hospital in Tennessee pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(37), and the following additional requirements:

1. Is enrolled for reimbursement as a rural emergency hospital by the federal Centers for Medicare and Medicaid Services pursuant to 42 U.S.C. §§ 1395x(kkk) et. seq. and 42 U.S.C. § 1395cc(j), or any successor statute;

2. Provides rural emergency hospital services;

3. Provides an emergency department which maintains:

   (i) Availability twenty-four (24) hours a day seven (7) days per week.

   (ii) A physician, physician assistant, or nurse practitioner, who performs such services as such individual is legally authorized to perform in accordance with state law and who meets training, education, and experience requirements required by state law.

   (iii) Such clinician must be on call at all times and available on-site within thirty (30) minutes to sixty (60) minutes depending on the facility's location.

   (iv) Staffed twenty-four (24) hours per day and (7) seven days per week by individuals competent in the skills needed to address emergency medical care and must be able to receive patients and activate appropriate medical resources to meet the care needed by patients.

4. Has a transfer agreement in effect with a level I or level II trauma center; and

5. Meets such other licensure, staff training and education requirements as the Health Facilities Commission finds necessary in the interest of the health and safety of individuals who are provided rural emergency hospital services.

6. A Rural Emergency Hospital does not have inpatient beds or provide any acute inpatient services, other than those which are rendered by a licensed skilled nursing facility to furnish post-hospital extended care services, which is a distinct part unit of the Rural Emergency Hospital.

7. Nothing in this definition expands on the scope of a licensed healthcare professional's ability to practice under their respective regulated profession.

~~(81)~~(101) Rural Emergency Hospital Services. The term "rural emergency hospital services" means the following services, provided by a Rural Emergency Hospital, that do not exceed an annual per-patient average of twenty-four (24) hours in such Rural Emergency Hospital:

(a) Emergency department services, and observation care; and

(b) At the election of the Rural Emergency Hospital, for services provided on an outpatient basis, other medical and health services as specified in regulations adopted by the United States Secretary of Health and Human Services and authorized by the applicable rules or statutes of the Health Facilities Commission.

(102) S.T.A.B.L.E. (Sugar, Temperature, Airway, Blood pressure, Lab work, Emotional support). Is a neonatal educational program that focuses on the post-resuscitation and stabilization of newborns.

~~(82)~~(103) Satellite Hospital. A freestanding hospital licensed with a parent hospital that is on separate premises and operated under the same management.

~~(83)~~(104) Shall or Must. Compliance is mandatory.

~~(84)~~(105) Social Worker. A person who has at least a bachelor's degree in Social Work or related field, and preferably, two (2) years medical social work or other community based work experience.

~~(85)~~(106) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified

medical personnel when a physician is not readily available.

~~(86)~~(107) 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.

~~(87)~~(108) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board.

~~(88)~~(109) 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.

~~(89)~~(110) Surgical Technologist. A person who works under supervision to facilitate the safe and effective conduct of invasive surgical procedures. This individual is usually employed by a hospital, medical office, or surgical center and supervised during the surgical procedure according to institutional policy and procedure to assist in providing a safe operating room environment that maximizes patient safety by performing certain tasks including, but not limited to:

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

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

(c) Passing instruments, equipment or supplies to a surgeon, sponging or suctioning an operative site, preparing and cutting suture material, holding retractors, transferring but not administering fluids or drugs, assisting in counting sponges, needles, supplies, and instruments, and performing other similar tasks as directed during a surgical procedure.

~~(90)~~(111) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(112) T-Piece Resuscitator. Is devised of a T shaped circuit which is utilized in neonatal resuscitation to deliver positive pressure ventilation (PPV). To determine a consistent, Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP) the operator can adjust the dials on the device.

(113) Tennessee Initiative for Perinatal Quality Care (TIPQC). Implements evidence-based practices focusing on enhancing health outcomes for mothers and newborns throughout Tennessee. Founded in 2008 through a grant from the Governor's Office to engage hospitals, practitioners, payers, families, and communities to promote meaningful change [illegible] and improve the quality of care through pregnancy, delivery and beyond for all Tennessee families.

(114) Tennessee Hospital Association (THA). Established in 1938, THA is a not-for-profit membership organization serving and promoting the interests of hospitals, health systems, and other healthcare organizations in the state.

(115) Tennessee Perinatal Care System Educational Objectives for Nurses. Developed by a group of experienced obstetric and neonatal nurse educators, [illegible] knowledge and skills necessary to provide quality nursing care to mothers and newborns.

(116) Tennessee Perinatal Care System Educational Objectives in Medicine for Perinatal Social W[illegible] objectives ensuring social workers are equipped to improve [illegible] d in[illegible] by enhancing the knowledge and skills essential in [illegible]

(117) Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing, and Facilities 2020 Edition. Guidelines are written in response to the recommendation

of the Perinatal Advisory Committee, describe components of various care levels, and are developed to accomplish improvement in perinatal outcomes in Tennessee by providing quality care to every mother and newborn.

(118) Tennessee Perinatal Care System Guidelines for Transportation. Guidelines are written in response to the recommendation of the Perinatal Advisory Committee and are developed to accomplish improvement in the overall quality of maternal-neonatal transportation in the state. The guidelines provide specific guidelines regarding procedures, staffing patterns, and equipment for the transport of high-risk mothers and infants.

(119) Total Parenteral Nutrition (TPN). Is delivered through a PICC (Peripherally Inserted Central Catheter – a catheter inserted into the inner aspect of the bend of the arm or the middle of the upper arm) line, subclavian or internal jugular veins. TPN is typically administered when a patient requires extensive nutritional support that cannot be achieved by any other means.

~~(91)~~(120) Transfer. The movement of a patient between hospitals at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice. The term does not apply to the commitment and movement of mentally ill and mentally retarded persons and does not apply to the discharge or release of a patient no longer in medical need of hospital care or to a hospital's refusal, after an appropriate medical screening, to render any medical care on the grounds that the person does not have a medical need for hospital care.

~~(92)~~(121) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(93)~~(122) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such person may be deemed to be the "treating physician."

~~(94)~~(123) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a hospital with any hospital employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1602; 68-11-1802, 68-57-101, 68-57-102, and 68-57-105; 42 U.S.C. § 1395x(kkk); and 42 U.S.C. § 1395cc(j).* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed November 30, 1984; effective December 30, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 26, 1996; effective July 8, 1996. Amendment filed November 30, 1999; effective February 6, 2000. Repeal, except for Paragraphs (1), (5), (8), (10), (11), (13), (16), (29), and (37) as promulgated February 6, 2000, and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed August 27, 2004; effective November 10, 2004. Amendments filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendments filed March 18, 2010; effective June 16, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed April 25, 2016; effective July 24, 2016. Amendments filed July 10, 2018; effective October 8, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022. Emergency rules filed December 27, 2022; effective through June 25, 2023. Emergency rules expired effective June 26, 2023, and the rules reverted to their previous statuses. Amendments filed August 11, 2023; effective November 9, 2023.*

**0720-14-.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 hospital 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 and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the hospital.~~

(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 hospital or any of the following optional services; Burn Unit, MRI Unit, NICU, or PET Unit 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 and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the hospital.

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

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

(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 based on the number of hospital beds. 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 hospital until a license has been issued. Applicants shall not hold themselves out to the public as being a hospital 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 T.C.A. § 68-11-206(1), or as later amended, and of all information required by the Commissioner.~~

(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. Patients shall not be admitted to the hospital until a license has been issued. Applicants shall not hold themselves out to the public as being a hospital 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 T.C.A. § 68-11-206(1), or as later amended, and of all information required by the Commission.

(d) The applicant must prove the ability to meet the financial needs of the facility.

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

~~(f) The applicant shall allow the hospital to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.~~

(f) The applicant shall allow the hospital 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) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.~~

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Commission a minimum of thirty (30) 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 a hospital 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 the hospital's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the hospital is owned and operated.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled;

7. The consolidation of a corporate facility owner with one or more corporations; or,

8. Transfers between levels of government.

9. 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; or,

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.

7. Management agreements where the owner continues to retain ultimate authority for the operation of the facility.

~~(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.~~

~~(f)~~(e) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

~~(4) Each hospital, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the department a fee based on the number of hospital beds, as follows:~~

(4) Each hospital, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the Commission a fee based on the number of hospital beds, as follows:

| | | |
|---|---|---|
| (a) | Less than 25 beds | $ 1,040.00 |
| (b) | 25 to 49 beds, inclusive | $ 1,300.00 |
| (c) | 50 to 74 beds, inclusive | $ 1,560.00 |
| (d) | 75 to 99 beds, inclusive | $ 1,820.00 |
| (e) | 100 to 124 beds, inclusive | $ 2,080.00 |
| (f) | 125 to 149 beds, inclusive | $ 2,340.00 |
| (g) | 150 to 174 beds, inclusive | $ 2,600.00 |
| (h) | 175 to 199 beds, inclusive | $ 2,860.00 |

For hospitals of two hundred (200) beds or more the fee shall be two thousand eight hundred and sixty dollars ($2,860.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(5) Each hospital choosing to operate one of the following optional services shall pay annually to the Commission a per unit non-refundable fee, as follows:

| | | |
|---|---|---|
| (a) | Burn Unit | $ 1,040.00 |
| (b) | NICU | $ 1,040.00 |
| (c) | MRI Unit | $ 500.00 |
| (d) | PET Unit | $ 500.00 |

~~(5)~~(6) Renewal.

~~(a) In order to renew a license, each hospital shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.~~

(a) In order to renew a license, each hospital 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 corrective action 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) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

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

(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 0720-14-.02(4); and

~~3. Any other information required by the Health Services and Development Agency.~~

3. Any other information required by the Commission.

~~(d) Upon reapplication, the licensee shall submit to an inspection of the hospital by Department of Health surveyors.~~

(d) Upon reapplication, the licensee shall submit to an inspection of the hospital by Commission surveyors.

***Authority:*** *T.C.A. §§ 4-5-201, 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-206(a)(5), 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, § 1.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed January 16, 1992; effective March 2, 1992. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed March 21, 2018; to have been effective June 19, 2018. However, on May 24, 2018, the Government Operations Committee filed a 5-day stay; new effective date June 24, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.03 DISCIPLINARY PROCEDURES.**

~~(1) The board may suspend or revoke a license for:~~

(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;

(c) Permitting, aiding or abetting the commission of any illegal act in the hospital;

~~(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the hospital; and~~

(d) Conduct or practice found by the Commission to be detrimental to the health, safety, or welfare of the patients of the hospital; and

(e) Failure to renew license.

~~(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:~~

(2) The Commission may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

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

~~(d) Any prior violations by the facility of statutes, regulations or orders of the board.~~

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

(3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke a hospital's license.

~~(4) When a hospital 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 deficiencies, the hospital must return a plan of correction indicating the following:~~

(4) When a hospital is found by the Commission to have committed a violation of this chapter, the Commission will issue to the facility a statement of deficiencies. Within ten (10) calendar days of the receipt of the deficiencies, the hospital 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.

~~(5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the hospital's license to possible disciplinary action.~~

(5) 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 the hospital's license to possible disciplinary action.

~~(6) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §§ 4-5-101, et seq.~~

(6) 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 Commission's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §§ 4-5-101, et seq.

~~(7) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to Rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.~~

(7) 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.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-208, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed December 30, 1986; effective February 13, 1987. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed March 1, 2007; effective May 15, 2007. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.04 ADMINISTRATION.**

(1) The hospital must have an effective governing body legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this chapter.

(2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital. 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 hospital with administrative direction at all times.

(3) When licensure is applicable for a particular job, the number and renewal number of the current license or a copy of the internet verification of such license must be maintained in personnel. 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.

(4) 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 hospital which violates a required policy also violates the rule and regulation establishing the requirement.

(5) Policies and procedures shall be consistent with professionally recognized standards of

practice.

~~(6) No hospital 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. A hospital 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.~~

(6) No hospital 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 hospital 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.

(7) The hospital shall ensure a framework for addressing issues related to care at the end of life.

(8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(9) Critical Access Hospital.

(a) The facility shall enter into agreements with one or more hospitals participating in the Medicare/Medicaid programs to provide services which the Critical Access Hospital is unable to provide.

(b) When there are no inpatients, the facility is not required to be staffed by licensed medical professionals, but must maintain a receptionist or other staff person on duty to provide emergency communication access. The hospital shall provide an effective system to ensure that a physician or a mid-level practitioner with training and experience in emergency care is on call and immediately available by telephone or radio and available on site within thirty (30) minutes, twenty-four (24) hours a day.

(10) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

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

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

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

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

(11) "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.

(12) Hospice services may be provided in an area designated by a hospital for exclusive use by a home care organization certified as a hospice provider to provide care at the hospice inpatient

or respite level of care in accordance with the hospice's Medicare certification. Admission to the hospital is not required in order for a patient to receive such hospice services, regardless of the patient's length of stay. The designation by a hospital of a portion of its facility for exclusive use by a home care organization to provide hospice services to its patients shall not:

(a) Alter the license to bed complement of such hospital, or

(b) Result in the establishment of a residential hospice.

(13) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

(14) Informed Consent.

(a) Any hospital in which abortions, other than abortions necessary to prevent the death of the pregnant female, are performed shall conspicuously post a sign in a location defined below so as to be clearly visible to patients, which reads:

Notice: It is against the law for anyone, regardless of the person's relationship to you, to coerce you into having or to force you to have an abortion. By law, we cannot perform an abortion on you unless we have your freely given and voluntary consent. It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.

(b) The sign shall be printed in languages appropriate for the majority of clients of the hospital with lettering that is legible and that is Arial font, at least 40-point bold-faced type.

(c) A hospital in which abortions are performed that is not a private physician's office or ambulatory surgical treatment center shall post the required sign in the admissions or registration department used by patients on whom abortions are performed.

~~(d) A hospital shall be assessed a civil penalty by the Board for Licensing Health Care Facilities of two thousand five hundred dollars ($2,500.00) for each day of violation in which:~~

(d) A hospital shall be assessed a civil penalty by the Commission of two thousand five hundred dollars ($2,500.00) for each day of violation in which:

1. The sign required above was not posted during business hours when patients or prospective patients are present; and

2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the hospital.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 39-15-202, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268, and 71-6-121.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendments filed February 22, 2010; effective May 23, 2010. Amendment filed December 16, 2013; effective March 16, 2014. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.**

(1) Every person admitted for care or treatment as an inpatient to any hospital covered by these rules shall be under the supervision of a physician who holds an unlimited license to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to a hospital by licensed health care professional, licensed to practice in Tennessee with the concurrence of a credentialed MD/DO also licensed to practice in Tennessee if admission by a category of licensed health care professionals is provided for in the medical staff bylaws. The licensed health care professional may also provide on call services to patients in the hospital if on call services for a category of licensed health care professionals is so provided for in the medical staff bylaws. The name of the attending licensed health care professional shall be recorded in the patient medical record as well as the name of the credentialed MD/DO. If a hospital allows these licensed health care professionals to admit and care for patients, as allowed by state law, the governing body and medical staff shall establish policies and bylaws, if necessary, to ensure that the requirements of 42 CFR part 482 are met.

(3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.

(4) A diagnosis must be entered in the admission records of the hospital for every person admitted for care or treatment.

(5) Except in emergency situations, no medication or treatment shall be given or administered to any inpatient in a hospital except on the order of a physician, dentist, or podiatrist lawfully authorized to give such an order. This requirement shall not apply to physical therapy, occupational therapy or speech language pathology services being provided in an outpatient setting when the services are being provided consistent with the scope of practice of physical therapists, occupational therapists and speech language pathologists as set forth in their respective practice acts found in Tennessee Code Annotated, Title 63, Chapters 13 and 17.

(6) 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.

(7) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established hospital protocol or rules.

(8) The hospital must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The hospital's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission of any patient who is likely to suffer adverse health consequences;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician;

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-hospitalization environment;

(e) Identify the patient's continuing physical, emotional, housekeeping, transportation, social and other needs and must make arrangements to meet those needs;

(f) Be completed on a timely basis to allow for arrangement of post-hospital care and to avoid unnecessary delays in discharge;

(g) Involve the patient, the patient's family or individual acting on the patient's behalf, the attending physician, nursing and social work professionals and other appropriate staff, and must be documented in the patient's medical record; and

(h) Be conducted on an ongoing basis throughout the continuum of hospital care. Coordination of services may involve promoting communication to facilitate family support, social work, nursing care, consultation, referral or other follow-up.

(9) A discharge plan is required on every patient, even if the discharge is to home.

(10) The hospital must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(11) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-hospital care.

(12) The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

(13) The governing body of each hospital must adopt transfer and acceptance policies and procedures in accordance with these rules and the provisions of T.C.A. §§ 68-11-701 through 68-11-705. These policies must include a review of all such involuntary transfers, with special emphasis on those originating in the emergency room.

(14) Transfer agreements with other health care facilities are subject to these statutory and regulatory provisions.

(15) When a hospital proceeding in compliance with these rules seeks to appropriately transfer a patient to another hospital, the proposed receiving hospital may not decline the transfer for reasons related to the patient's ability to pay or source of payment, rather than the patient's need for medical services. The determination of the availability of space at the receiving hospital may not be based on the patient's ability to pay or source of payment.

(16) Anyone arriving at a hospital and/or the emergency department of a hospital requesting or requiring an examination or treatment for a medical condition must be provided an appropriate medical screening examination within the capability of the hospital's staff to determine whether or not a medical emergency exists.

(17) The hospital must provide further medical examination and treatment as may be required to stabilize the medical emergency within the hospital's available staff and facilities. Such treatment may include, but is not limited to, the following:

(a) Establishing and assuring an adequate airway and adequate ventilation;

(b) Initiating control of hemorrhage;

(c) Stabilizing and splinting the spine or fractures;

(d) Establishing and maintaining adequate access routes for fluid administration;

(e) Initiating adequate fluid and/or blood replacement; and

(f) Determining that the patient's vital signs (including blood pressure, pulse, respiration, and urinary output, if indicated) are sufficient to sustain adequate perfusion.

(18) A hospital is deemed to meet the requirements of this section with respect to an individual if:

(a) The hospital offers to provide the further medical examination and treatment necessary but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the examination or treatment; or

(b) The hospital offers to transfer the individual to another hospital in accordance with this section but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the transfer.

(19) If a patient at a hospital has not been or cannot be stabilized within the meaning of this section, the hospital may not transfer the patient unless:

(a) The patient, or legally responsible person acting on the patient's behalf, requests that a transfer be implemented after having been given complete and accurate information about matters pertaining to the transfer decision including:

1. The medical necessity of the movement;

2. The availability of appropriate medical services at both the transferring and receiving hospitals;

3. The availability of indigent care at the hospital initiating the transfer and the facility's legal obligations, if any, to provide medical services without regard to the patient's ability to pay; and,

4. Any obligation of the hospital through its participation in medical assistance programs of the federal, state or local government to accept the medical assistance program's reimbursement as payment in full for the needed medical care.

(b) A physician, or other appropriately qualified medical personnel when a physician is not available, makes a determination based upon the reasonable risk, expected benefits to the patient, and current available information that the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risk to the individual's medical condition resulting from a transfer; and

(c) The transfer is appropriate within the meaning of this section.

(20) An appropriate transfer includes:

(a) A physician at the receiving hospital agreeing to accept transfer of the patient and to provide appropriate medical treatment;

(b) The receiving hospital having space available and personnel qualified to treat the patient;

(c) The transferring hospital providing the receiving hospital with appropriate medical records, or copies thereof, of any examination and/or treatment initiated by the

transferring hospital; and

(d) The transfer being effected with qualified personnel, appropriate transportation equipment, and the use of necessary and medically appropriate life support measures as required.

~~(21) Transfers made pursuant to a regionalized plan for the delivery of health care services, approved by the department or other authorized governmental planning agency, are presumed to be appropriate.~~

(21) Transfers made pursuant to a regionalized plan for the delivery of health care services, approved by the Commission or other authorized governmental planning agency, are presumed to be appropriate.

(22) After an appropriate transfer has been effected, the receiving hospital may transfer the patient back to the original hospital, and the original hospital may accept the patient, if:

(a) The original receiving hospital has stabilized the medical emergency or provided treatment of the active labor and the patient no longer has a medical emergency; and

(b) The transfer is made in accordance with (21) of this section.

~~(23) When a hospital determines the need to exceed its licensed bed capacity upon an occurrence of a justified emergency, the following procedures must be followed:~~

(23) When a hospital determines the need to exceed its licensed bed capacity upon an occurrence of a justified emergency, one of the following procedures must be followed:

(a) Short term need to exceed licensed bed capacity for a justified emergency

~~1. The hospital's administrator must make written notification to the Department within forty-eight (48) hours of exceeding its licensed bed capacity.~~

1. The hospital's administrator must make written notification to the Commission within forty-eight (48) hours of exceeding its licensed bed capacity.

2. The notification must include a detailed description of the emergency including:

(i) Why the licensed bed capacity was exceeded, i.e., lack of hospital beds in vicinity, specialized resources only available at the facility, etc.;

(ii) The estimated length of time the licensed bed capacity is expected to be exceeded; and,

(iii) The number of admissions in excess of the facility's licensed bed capacity.

~~3. As soon as the hospital returns to its licensed bed capacity, the administrator must notify the department in writing of the effective date of its return to compliance.~~

3. As soon as the hospital returns to its licensed bed capacity, the administrator must notify the Commission in writing of the effective date of its return to compliance.

~~4. Staff will review all notifications of excess bed capacity with the Chairman of the Board. If, upon review of the notification, department staff concurs that a justified emergency existed, staff will notify the facility in writing. A report of the occurrence will be made to the board at the next regularly scheduled meeting as information purposes only.~~

4. Staff will review all notifications of excess bed capacity with the Chairman of the Commission. If, upon review of the notification, Commission staff concurs that a justified emergency existed, staff will notify the facility in writing. A report of the occurrence will be made to the Commission at the next regularly scheduled meeting as information purposes only.

~~5. However, if department staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled board meeting to justify the need for exceeding its licensed bed capacity.~~

5. However, if Commission staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled Commission meeting to justify the need for exceeding its licensed bed capacity.

(b) Request a waiver of bed capacity not to exceed three (3) months.

1. If a waiver is being requested, notification must be given at the next regularly scheduled Commission meeting and include all of the following:

(i) Provide the number of beds requested under the waiver;

(ii) Provide the reason for the increase in bed capacity to include a description of the illness causing the need;

(iii) Provide an attestation that the required staffing levels can be met;

(iv) Provide the average expected length of stay;

(v) Provide an attestation that staffing levels can be maintained if the expected length of stay is exceeded; and

(vi) Provide a description of the location and area of the overflow

2. Administrative staff will review the request and may:

(i) Administratively approve the waiver; or

(ii) Administratively approve the waiver with conditions to protect the health, safety, and the welfare of the patients; or

(iii) Deny the waiver and request appearance before the Commission at the next regularly scheduled commission meeting.

(24) Infant Abandonment.

(a) Any hospital shall receive possession of any newborn infant left on hospital premises with any hospital employee or member of the professional medical community, if the infant:

1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;

2. Is left in an unharmed condition; and

3. Is voluntarily left by a person who purported to be the child's mother and who did not express

an intention of returning for the infant.

(b) The hospital, any hospital employee and any member of the professional medical community at such hospital shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The hospital shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The hospital may provide the parent contact information regarding relevant social service agencies, shall provide the mother the name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinquishment of the infant. If practicable, the hospital shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.

(c) The hospital, any hospital employee and any member of the professional medical community at such hospital shall perform any act necessary to protect the physical health or safety of the child.

(d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the hospital shall contact the Department of Children's Services, but shall not do so before the mother leaves the hospital premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.

(e) Notwithstanding any provision of law to the contrary, any hospital, any hospital employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause of action based upon violation of such existing standard of care for medical treatment.

(25) Caregiver.

(a) The hospital shall give a patient admitted to the hospital the opportunity to designate a caregiver who will assist the patient with continuing care after discharge from the hospital.

1. Caregiver means any individual designated as a caregiver by a patient who provides after-care assistance to a patient in a private residence. The term includes, but is not limited to, a relative, spouse, partner, friend or neighbor who has a significant relationship with the patient.

2. The hospital shall document the designated caregiver in the patient record and include contact information; and

3. If the patient declines to designate a caregiver, the hospital shall document the patient's choice in the medical record.

(b) The hospital shall notify the designated caregiver as soon as practicable before the patient is discharged back to a private residence.

(c) If the hospital is unable to contact the designated caregiver when changes occur, the lack of contact shall not interfere with, delay or otherwise affect the medical care provided to the patient or the transfer or discharge of the patient. Nothing in this paragraph shall interfere with, delay or otherwise affect the medical care provided to the patient or the transfer or discharge of the patient.

(d) The hospital shall make reasonable efforts to contact the designated caregiver and document those efforts in the patient record, to include dates and times attempted.

(e) The patient may give written consent to allow the hospital to release medical information to the designated caregiver, pursuant to the hospital's established procedures for the release of personal health information.

(f) Prior to the patient being discharged, the hospital shall provide discharge instructions for continuing care needs to the patient and designated caregiver, which shall include:

1. The name and contact information of the designated caregiver and relation to the patient;

2. A description of continuing care tasks that the patient requires, communicated in a culturally competent manner; and

3. Contact information for any health care, community resources, and long-term services and supports necessary to successfully carry out the patient's discharge instructions.

(g) Prior to the patient being discharged, the hospital shall provide the designated caregiver with an opportunity for instruction in continuing care tasks outlined in the discharge instructions, which shall include:

1. Demonstration of the continuing care tasks by hospital personnel; and

2. Opportunity for the patient and designated caregiver to ask questions and receive answers regarding the continuing care tasks; and

3. Education and counseling about medications, including dosing and proper use of delivery devices.

(h) The hospital shall document the instruction given to the patient and designated caregiver in the patient record, to include the date, time and contents of the instructions.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, and 68-11-255.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002. Amendments filed July 10, 2018; effective October 8, 2018. Amendments filed January 7, 2019; to have become effective April 7, 2019. However, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 6, 2019. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.06 BASIC HOSPITAL FUNCTIONS.**

(1) Performance Improvement.

(a) The hospital must ensure that there is an effective, hospital-wide performance improvement program to evaluate and continually improve patient care and performance of the organization.

(b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:

1. All organized services including services furnished by a contractor, are evaluated (all departments including engineering, housekeeping, and accounting need to show evidence of process improvement.);

2. Nosocomial infections and medication therapy are evaluated;

3. All medical and surgical services performed in the hospital are evaluated as to the appropriateness of diagnosis and treatment;

4. The competency of all staff is evaluated at least annually; and

5. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program, central venous catheter insertion process, and influenza vaccination program.

(c) The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically related needs of its patients which assures that:

1. Discharge planning is initiated in a timely manner; and

2. Patients, along with their necessary medical information, are transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.

(d) The hospital must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action.

(e) The hospital must demonstrate that the appropriate governing board or board committee is regularly apprised of process improvement activities, including identified deficiencies and the outcomes of remedial action.

(2) Medical Staff.

(a) The hospital shall have an organized medical staff operating under bylaws adopted by the medical staff and approved by the governing body, to facilitate the medical staff's responsibility in working toward improvement of the quality of patient care.

(b) The hospital and medical staff bylaws shall contain procedures, governing decisions or recommendations of appropriate authorities concerning the granting, revocation, suspension, and renewal of medical staff appointments, reappointments, and/or delineation of privileges. At a minimum, such procedures shall include the following elements: A procedure for appeal and hearing by the governing body or other designated committee if the applicant or medical staff feels the decision is unfair or wrong.

(c) The governing body shall be responsible for appointing medical staff and for delineating privileges. Criteria for appointment and delineation of privileges shall be clearly defined and included in the medical staff bylaws, and related to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the individual practitioner. Independent patient admission privileges shall only be granted to currently licensed doctors of medicine, osteopathy, podiatry, or dentistry.

(d) The medical staff must adopt and enforce bylaws to effectively carry out its responsibilities and the bylaws must:

1. Be approved by the governing body;

2. Include a statement of the duties and privileges of each category of medical staff;

3. Describe the organization of the medical staff;

4. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;

5. Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges; and

6. Include provisions for medical staff appointments granting active, associate, or courtesy medical staff membership, and/or provisions for the granting of clinical privileges. Such individuals must practice within the scope of their current Tennessee license, and the overall care of each patient must be under the supervision of a physician member of the medical staff.

(e) To be eligible for staff membership, an applicant must be a graduate of an approved program of medicine, dentistry, osteopathy, podiatry, optometry, psychology, or nurse-midwifery, currently licensed in Tennessee, competent in his or her respective field, and worthy in character and in matters of professional ethics.

(f) The medical staff shall be composed of currently licensed doctors of medicine, osteopathy, dentistry, and podiatry and may include optometrists, psychologists, and nurse-midwives. The medical staff must:

1. Periodically conduct appraisals of its members;

2. Examine the credentials of candidates for medical staff membership and make recommendations to the hospital on the appointment of the candidates; and

3. Participate actively in the hospital's process improvement plan implementation for the improvement of patient care delivery plans.

(g) The medical staff must be structured in a manner approved by the hospital or its governing body, well-organized, and accountable to the hospital for the quality of the medical care provided to the patient. Disciplinary action involving medical staff taken by the hospital shall be reported to the appropriate licensing board or professional society.

(h) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(i) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy, or a doctor of dental surgery or dental medicine.

(j) All physicians and non-employee medical personnel working in the hospital must adhere to the policies and procedures of the hospital. The Chief Executive officer or his or her designee shall provide for the adequate supervision and evaluation of the clinical activities of non-employee medical personnel which occur within the responsibility of the medical staff service.

(3) Infection Control.

(a) The hospital 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 chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff

develop guidelines and techniques for the prevention, surveillance, control and reporting of hospital infections. Duties of the committee shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the hospital;

3. Written procedures governing the use of aseptic techniques and procedures in all areas of the hospital, including adoption of a standardized central venous catheter insertion process which shall contain these key components:

   (i) Hand hygiene (as defined in 0720-14-.06(3)(g));

   (ii) Maximal barrier precautions to include the use of sterile gowns, gloves, mask and hat, and large drape on patient;

   (iii) Chlorhexidine skin antisepsis;

   (iv) Optimal site selection;

   (v) Daily review of line necessity; and

   (vi) Development and utilization of a procedure checklist;

4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A log of incidents related to infectious and communicable diseases;

6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;

7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies;

8. and Continuing education provided for all hospital personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.

(c) The administrative staff shall ensure the hospital prepares, and has readily available on site, an Infection Control Risk Assessment for any renovation or construction within existing hospitals. Components of the Infection Control Risk Assessment may include, but are not limited to, identification of the area to be renovated or constructed, patient risk groups that will potentially be affected, precautions to be implemented, utility services subject to outages, risk of water damage, containment measures, work hours for project, management of traffic flow, housekeeping, barriers, debris removal, plans for air sampling during or following project, anticipated noise or vibration generated during project.

(d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the hospital wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.

(e) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(f) A hospital 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 hospital 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 https://www.tn.gov/content/dam/tn/health/documents/SampleIndividualFluForm.pdf);

3. Education of all employees about the following:

(i) Flu vaccination,

(ii) Non-vaccine control measures, and

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

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

~~5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.~~

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

(g) All hospitals shall each year from October 1 through March 1offer the immunization for influenza and pneumococcal diseases to any inpatient who is sixty-five (65) years of age or older prior to discharging. This condition is subject to the availability of the vaccine.

(h) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:

1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;

2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;

3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and

4. Health care worker education programs which may include:

(i) Types of patient care activities that can result in hand contamination;

(ii) Advantages and disadvantages of various methods used to clean hands;

(iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and

(iv) Morbidity, mortality, and costs associated with health care associated infections.

(i) All hospitals 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.

(j) Each department of the hospital performing decontamination and sterilization activities must develop policies and procedures in accordance with the current editions of the CDC guidelines for "Prevention and Control of Nosocomial Diseases" and "Isolation in Hospitals".

(k) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including:

1. Receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing reusable items;

2. Assembling, wrapping, removal of outer shipping cartons, storage, distribution, and quality control of sterile equipment and medical supplies;

3. Proper utilization of sterilization process monitors, including temperature and pressure recordings, and use and frequency of appropriate chemical indicator or bacteriological spore tests for all sterilizers; and

4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies;

5. Procedures for recall and disposal or reprocessing of sterile supplies; and

6. Procedures for emergency collection and disposition of supplies and the timely notification of attending physicians, general medical staff, administration and the hospital's risk management program when special warnings have been issued or when warranted by the hospital's performance improvement process.

(l) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Sterile supplies may not be stored in their outermost shipping carton. This would include both hospital and commercially prepared supplies. Decontamination and preparation areas shall be separated.

(m) Space and facilities for housekeeping equipment and supply storage shall be provided in each hospital service area. Storage for bulk supplies and equipment shall be located away from patient care areas. Storage shall not be allowed in the outermost shipping carton. The building shall be kept in good repair, clean, sanitary and safe at all times.

(n) The hospital shall appoint a housekeeping supervisor who is qualified for the position by education, training and experience. The housekeeping supervisor shall be responsible for:

1. Organizing and coordinating the hospital's housekeeping service;

2. Acquiring and storing sufficient housekeeping supplies and equipment for hospital maintenance;

3. Assuring the clean and sanitary condition of the hospital to provide a safe and hygienic environment for patients and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and hospital policy; and

4. Verifying regular continuing education and competency for basic housekeeping principles.

(o) Laundry facilities located in the hospital shall:

1. Be equipped with an area for receiving, processing, storing and distributing clean linen;

2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;

3. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the hospital. Linen may not be stored in cardboard containers or other containers which offer housing for bugs; and,

4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.

(p) The hospital shall appoint a laundry service supervisor who is qualified for the position by education, training and experience. The laundry service supervisor shall be responsible for:

1. Establishing a laundry service, either within the hospital or by contract, that provides the hospital with sufficient clean, sanitary linen at all times;

2. Knowing and enforcing infection control rules and regulations for the laundry service;

3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures;

4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures; and,

5. Conducting periodic inspections of any contract laundry facility.

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

1. Any condition on the hospital site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

2. Cats, dogs or other animals shall not be allowed in any part of the hospital except

for specially trained animals for the handicapped and except as addressed by facility policy for pet therapy programs. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

3. A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.

4. Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.

5. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.

6. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.

(4) Nursing Services.

(a) The hospital must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times.

(b) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The chief nursing officer must be a licensed registered nurse who is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(c) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(d) There must be a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licenses.

(e) A registered nurse must assess, supervise and evaluate the nursing care for each patient.

(f) The hospital must ensure that an appropriate individualized plan of care is available for each patient.

(g) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. All nursing personnel assigned to special care units shall have specialized training and a program in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed, along with documentation of annual

competency skills.

(h) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:

1. The deceased was a patient at a hospital as defined by T.C.A. § 68-11-201(27);

2. Death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;

3. The nurse is licensed by the state; and

4. The nurse is employed by the hospital providing services to the deceased.

(i) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The chief nursing officer must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. Annual competency and skill documentation must be demonstrated on these individuals just as employees, if they perform clinical activities.

(j) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(k) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they must be:

1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and

2. Signed or initialed by the prescribing practitioner according to hospital policy.

(l) Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

(m) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(5) Medical Records.

(a) The hospital shall comply with the Tennessee Medical Records Act, T.C.A. §§ 68-11-301, et seq. A hospital shall transfer copies of patient medical records in a timely manner to requesting practitioners and facilities.

(b) The hospital must have a medical record service that has administrative responsibility for medical records. The service shall be supervised by a Registered Health Information Administrator (RHIA), a Registered Health Information Technician (RHIT), or a person qualified by work experience. A medical record must be maintained for every individual evaluated or treated in the hospital.

(c) The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing and retrieval of records.

(d) The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(e) All medical records, either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years, or for the period of minority plus one year for newborns, after which such records may be destroyed. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of its contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the hospital's policies and procedures, and no record may be destroyed on an individual basis.

~~(f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the department. Upon transfer to the department, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.~~

(f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the Tennessee Department of Health. Upon transfer to the Tennessee Department of Health, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.

(g) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.

(h) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with federal and state laws, court orders or subpoenas.

(i) The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(j) All entries must be legible, complete, dated and authenticated according to hospital policy.

(k) All records must document the following:

1. Evidence of a physical examination, including a health history, performed and/or updated no more than forty-five (45) days prior to admission or within forty-eight (48) hours following admission;

2. Admitting diagnosis;

3. Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

4. Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;

5. Properly executed informed consent forms for procedures and treatments specified by hospital policy, or by federal or state law if applicable, as requiring written patient consent;

6. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;

7. Discharge summary with outcome of hospitalization, disposition of case and plan for follow-up care; and

8. Final diagnosis with completion of medical records within thirty (30) days following discharge.

(l) Electronic and computer-generated records and signature entries are acceptable.

(6) Pharmaceutical Services.

(a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(b) A full-time, part-time or consulting pharmacist must be responsible for developing, supervising and coordinating all the activities of the pharmacy services.

(c) Current and accurate records must be kept of receipt and disposition of all scheduled drugs.

(d) Adverse drug events, both adverse reactions and medication errors, shall be reported according to established guidelines to the hospital performance improvement/risk management program and as appropriate to physicians, the hospital governing body and regulatory agencies.

(e) Abuses and losses of controlled substances must be reported, in accordance with federal and state laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(f) Current reference materials relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff in the pharmacy and in areas where medication is administered.

(g) Any unused portions of prescriptions shall be either turned over to the patient only on a written authorization including directions by the physician, or returned to the pharmacy for proper disposition by the pharmacist.

(h) Whenever patients bring drugs into an institution, such drugs shall not be administered unless they can be identified and ordered to be given by a physician.

(7) Radiologic Services.

(a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(b) The radiologic services must be free from hazards for patients and personnel.

(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) Radiologic services must be provided only on the order of practitioners with clinical privileges or of other practitioners authorized by the medical staff and the governing body to order the services.

(f) X-ray personnel shall be qualified by education, training and experience for the type of service rendered.

(g) All x-ray equipment must be registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health.

(h) 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.

(i) Patients must not be left unattended in pre- and post-radiology areas.

(8) Laboratory Services.

(a) The hospital must maintain, or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act. All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.

(b) Emergency laboratory services must be available 24 hours a day.

(c) A written description of services provided must be available to the medical staff.

(d) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(e) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(f) Laboratory services must be provided in keeping with services rendered by the hospital. This shall include suitable arrangements for blood and plasma at all times. Written policies and procedures shall be developed in concert with the Standards of American Association of Blood Banks. Documentation and record keeping shall be maintained for tracking and performance monitoring.

(9) Food and Dietetic Services.

(a) The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. A hospital may contract with an outside food management company if the company has a dietitian who serves the hospital on a full- time, part-time,

or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment. If an outside contract is utilized for management of its dietary services, the hospital shall designate a full-time employee to be responsible for the overall management of the services.

(b) The hospital must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:

1. A qualified dietitian; or,

2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,

3. An individual who has successfully completed in-person or online coursework that provided ninety (90) or more hours of classroom instruction in food service supervision. If the course has not been completed, this person shall be enrolled in a course and making satisfactory progress for completion within the time limit specified by the course requirement; or,

4. An individual who is a certified dietary manager (CDM), or certified food protection professional (CFPP); or,

5. A current or former member of the U.S. military who has graduated from an approved military dietary manager training program.

(c) There must be a qualified dietitian, full-time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the patient and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.

(d) There must be sufficient administrative and technical personnel competent in their respective duties.

(e) Menus must meet the needs of the patients.

1. Individual patient nutritional needs must be met in accordance with recognized dietary practices.

2. All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian to whom the physician who chairs the hospital's medical executive committee has referred this task. The medical staff and hospital's board of trustees shall decide the extent of ordering privileges that a qualified dietitian shall have and a mechanism to ensure that order writing by a qualified dietitian is coordinated with the responsible practitioner's care of the patient and complies with Tennessee law governing dietitians.

3. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

(f) Education programs, including orientation, on-the-job training, inservice education, and continuing education programs shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in personal hygiene, proper inspection, handling, preparation and serving of food and equipment.

(g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs.

~~(h) All food shall be from sources approved or considered satisfactory by the department and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.~~

(h) All food shall be from sources approved or considered satisfactory by the Commission and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.

(i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual."

(j) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.

(10) Critical Access Hospital.

(a) Every patient shall be under the care of a physician or under the care of a mid-level practitioner supervised by a physician.

(b) Whenever a patient is admitted to the facility by a mid-level practitioner, the supervising physician shall be notified of that fact, by phone or otherwise, and within 24 hours the supervising physician shall examine the patient or before discharge if discharged within 24 hours, and a plan of care shall be placed in the patient's chart, unless the patient is transferred to a higher level of care within 24 hours.

(c) A physician, a mid-level practitioner or a registered nurse shall be on duty and physically available in the facility when there are inpatients.

(d) A physician on staff shall:

1. Provide medical direction to the facility's health care activities and consultation for non-physician health care providers.

2. In conjunction with the mid-level practitioner staff members, participate in developing, executing, and periodically reviewing the facility's written policies and the services provided to patients.

3. Review and sign the records of each patient admitted and treated by a practitioner no later than fifteen (15) days after the patient's discharge from the facility.

4. Provide health care services to the patients in the facility, whenever needed and requested.

5. Prepare guidelines for the medical management of health problems, including

conditions requiring medical consultation and/or patient referral.

6. At intervals no more than two (2) weeks apart, be physically present in the facility for a sufficient time to provide medical direction, medical care services, and staff consultation as required.

7. When not physically present in the facility, either be available through direct telecommunication for consultation and assistance with medical emergencies and patient referral, or ensure that another physician is available for this purpose.

8. The physical site visit for a given two week period is not required if, during that period, no inpatients have been treated in the facility.

(e) A mid-level practitioner on staff shall:

1. Participate in the development, execution, and periodic review of the guidelines and written policies governing treatment in the facility.

2. Participate with a physician in a review of each patient's health records.

3. Provide health care services to patients according to the facility's policies.

4. Arrange for or refer patients to needed services that are not provided at the facility.

5. Assure that adequate patient health records are maintained and transferred as necessary when a patient is referred.

(f) The Critical Access Hospital, at a minimum, shall provide basic laboratory services essential to the immediate diagnosis and treatment of patients, including:

1. Chemical examinations of urine stick or tablet methods, or both (including urine ketoses);

2. Microscopic examinations of urine sediment;

3. Hemoglobin or hematocrit;

4. Blood sugar;

5. Gram stain;

6. Examination of stool specimens for occult blood;

7. Pregnancy test;

8. Primary culturing for transmittal to a CLIA certified laboratory;

9. Sediment rate; and,

10. CBC.

(11) Rural Emergency Hospital.

(a) A hospital shall be eligible to apply for a Rural Emergency Health ("REH") designation as such and conversion to a Rural Emergency Hospital, if the facility, as of December 27th, 2020, was a:

~~1. Critical Access Hospital as defined under Tenn. Comp. R. & Regs. 0720-14-~~

~~.01(19); or~~

1. Critical Access Hospital as defined under Tenn. Comp. R. & Regs. 0720-14-.01(26); or

2. General hospital with no more than 50 licensed beds located in an area designated by state or federal law as a rural area; or

3. General hospital with no more than 50 licensed beds located in an area designated as rural under 42 U.S.C. § 1395ww(d)(8)(E), or any successor statute.

(b) A facility applying for designation as a Rural Emergency Hospital shall include in its licensure application:

1. A detailed transition plan that lists the services that the facility will retain, modify, add, and discontinue.

~~2. A description of services that the facility intends to furnish on an outpatient basis pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(83)(b).~~

2. A description of services that the facility intends to furnish on an outpatient basis pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(101)(b).

3. A description of any additional services the hospital would be supporting, such as furnishing telehealth services and ambulance services, including operating the facility and maintaining the emergency department to provide such services covered by these rules.

4. Any such other information as the rules and regulations of the Health Facilities Commission may require.

(c) A Rural Emergency Hospital may be allowed to own and operate an entity that provides ambulance services.

(d) A licensed general hospital or Critical Access Hospital that applies for and receives licensure as a Rural Emergency Hospital and elects to operate as a Rural Emergency Hospital shall retain its original license as a general hospital or Critical Access Hospital. Such original license shall remain inactive while the Rural Emergency Hospital license is in effect.

(e) A licensed Rural Emergency Hospital may enter into any contracts required to be eligible for federal reimbursement as a Rural Emergency Hospital.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-3-511, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105; 42 U.S.C. § 1395x(kkk); and 42 U.S.C. § 1395cc(j).* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendment filed March 18, 2010; effective June 16, 2010. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed July 18, 2016; effective October 16, 2016. Amendments filed July 10, 2018; effective October 8, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022. Emergency rules filed December 27, 2022; effective through June 25, 2023. Emergency rules expired effective June 26, 2023, and the rules reverted to their previous statuses. Amendments filed August 11, 2023; effective November 9, 2023.*

**0720-14-.07 OPTIONAL HOSPITAL SERVICES.**

(1) Surgical Services.

(a) If the hospital provides surgical services, the services must be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

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

(c) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

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

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

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

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

(h) The health facilities commission shall publish an approved list of accredited surgical technology programs.

1. Surgical technologists must meet one (1) or more of the following:

(i) Successfully completed a nationally accredited surgical technology program, and holds and maintains certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission;

(ii) Successfully completed an accredited surgical technologist program;

(I) Has not, as of the date of hire, obtained certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission; and

(II) Obtains such certification no later than eighteen (18) months after completion of the program.

(iii) Successfully completed a training program for surgical technology in the armed forces of the United States, the national guard, or the United States public health service; or

(iv) Performed surgical technology services as a surgical technologist in a healthcare facility on or before May 21, 2007, and has been designated by the healthcare facility as being competent to perform surgical technology services based on prior experience or specialized training validated by competency in current practice. The healthcare facility employing or retaining such person as a surgical technologist under this subsection (a) obtains proof of such person's prior experience, specialized training, and current continuing competency as a surgical technologist and makes the proof available to the health facilities commission upon request of the commission.

2. This section does not prohibit a person from performing surgical technology services if the person is acting within the scope of the person's license, certification, registration, permit, or designation, or is a student or intern under the direct supervision of a healthcare provider.

~~(i) A hospital can petition the director of health care facilities of the department for a waiver from the provisions of 0720-14-.07(1)(h) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.~~

(i) A hospital can petition the Commission for a waiver from the provisions of 0720-14-.07(1)(h) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the Commission that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The Commission shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Commission.

(j) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal. Persons qualified to be employed as surgical technologists shall complete fifteen (15) hours of continuing education or contact hours annually. Current certification by the National Board of Surgical Technology and Surgical Assisting shall satisfy this requirement.

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

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

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

1. Call-in system;

2. Cardiac monitor;

3. Resuscitator;

4. Defibrillator;

5. Aspirator; and

6. Tracheotomy set.

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

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

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

(2) Anesthesia Services.

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

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

1. A qualified anesthesiologist;

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

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

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

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

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

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

2. An intraoperative anesthesia record;

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

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

(3) Nuclear Medicine Services.

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

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

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

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

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

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

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

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

1. Maintained in safe operating condition; and,

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

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

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

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

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

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

(4) Outpatient Services.

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

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

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

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

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

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

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

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

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

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

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

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

(5) Emergency Services.

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

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

1. The hospital's physical geographic boundaries; or

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

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

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

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

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

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

assess, stabilize, treat and/or transfer patients.

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

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

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

(h) Legend drugs in emergency rooms shall be stored in locked cabinets, except as otherwise provided for emergency drugs by the written policies and procedures of the hospital. Discharge medications may be dispensed to out-patients upon written physician orders provided that they have been packaged in containers by the pharmacist in amounts not to exceed twelve (12) hours dosage and labeled in accordance with Pharmacy Board rules.

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

1. Identification data;

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

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

4. Significant physical findings;

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

6. Treatment rendered;

7. Condition of the patient on discharge or transfer;

8. Diagnosis on discharge;

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

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

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

(6) Rehabilitation Services.

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

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

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

(d) Physical therapy, occupational therapy, speech therapy, or audiology services, if

provided, must be provided by staff who meet the qualifications specified by hospital policy, consistent with state law.

(e) Services must be furnished in accordance with a written plan of treatment in accordance with the practice acts of the practitioners who are authorized by medical staff to provide the services. The written plan of treatment must be incorporated in the patient's record.

(7) Obstetrical Services.

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

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

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

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

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

1. The name of the patient;

2. Her maiden name;

3. Date of delivery;

4. Sex of infant;

5. Name of physician;

6. Names of persons assisting;

7. What complications, if any, occurred;

8. Type of anesthesia used;

9. Name of person administering anesthesia; and

10. Other persons present.

(8) Pediatric Services.

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

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

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

(9) Respiratory Care Services.

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

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

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

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

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

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

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

(10) Social Work Services.

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

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

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

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

(11) Psychiatric Services.

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

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

(b) A hospital licensed by the Commission as a satellite hospital whose primary purpose is

the provision of mental health or substance abuse services, must verify to the Commission that Standards of the Department of Mental Health and Substance Abuse Services are satisfied.

(12) Alcohol and Drug Services.

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

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

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

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

(14) Burn Unit Services.

(a) If a hospital provides Burn unit services, the following licensing requirements apply:

1. 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. Patients shall not be admitted to the burn until a license has been issued. Applicants shall not hold themselves out to the public as being a burn unit until the license has been issued.

(i) The applicant shall allow the burn unit to be inspected by Commission staff. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action within ten (10) calendar days 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.

(ii) A provisional license shall be issued upon administrative approval of the initial application.

(iii) A provisional licensee must achieve American Burn Association (ABA) verification within five (5) years of obtaining a provisional license. A provisional licensee must comply with the following requirements:

(I) Provide the Commission with annual progress reports demonstrating engagement and measurable efforts toward obtaining verification.

(II) Provide data to the Burn Care Quality Platform (BCQP) and provide reports formatted in accordance with Commission reporting requirements.

(III) Participate in annual onsite visits conducted by Commission staff, consultant burn surgeons and burn nurses until ABA verification is

achieved.

I. Site visits must be scheduled by within twelve (12) months of provisional licensure.

II. Costs associated with site visits shall be assessed to the provisional licensee by the Commission through the issuance of an Assessment of Costs.

2. A full license shall not be issued until the facility is ABA verified and written confirmation verification has been achieved is submitted to the Commission.

3. A fully licensed burn unit must maintain ABA verification. Loss of ABA verification will cause the full license to be reverted to a provisional license until re-verification is achieved

(b) If a hospital provides Burn Unit services, the following administrative requirements apply:

1. The burn unit must have a Burn Unit Director who is responsible for the following:

(i) All burn unit administrative functions.

(ii) Creation of policies and procedures regarding burn unit care.

(iii) Ensure burn unit staff are properly credentialed through the general hospital's medical staff credentialing process.

(iv) Ensure burn unit staff obtain and maintain Advanced Burn Life Support (ABLS) certification.

2. The burn unit must have a Burn Nurse Leader who is responsible for the following:

(i) All burn unit nursing functions.

(ii) Ensure burn unit nurses obtain and maintain Advanced Burn Life Support (ABLS) certification.

(iii) Participate in burn unit quality improvement meetings.

(15) MRI Services

(a) If a hospital provides MRI services, the following licensing requirements apply to each unit:

1. Must become accredited by a nationally recognized and CMS approved accrediting organization within one year of licensure per machine and per diagnostic type.

2. Must adhere to all federal and state regulations.

(16) NICU Services

(a) If a qualifying hospital provides NICU services, the following licensing requirements apply:

1. 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. Patients shall not be admitted to the NICU until a license has been issued.

Applicants shall not hold themselves out to the public as being a NICU unit until the license has been issued.

(i) The applicant shall allow the NICU to receive an initial inspection by Commission staff. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action within ten (10) calendar days 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.

(ii) A provisional license shall be issued upon administrative approval of the initial application.

(iii) Within three (3) years of obtaining a provisional license, licensee must achieve either:

(I) State level verification; or

(II) Verification through the American Academy of Pediatrics (AAP).

(iv) Upon application, applicant will self-designate. At verification, licensee must comply with the corresponding requirements based upon level of designation (for levels II-IV) as illustrated in the referenced levels of care;

(I) The verification process shall be based upon the standards established by and referenced within the Tennessee Perinatal Care System, Guidelines for Regionalization, Hospital Care Levels, Staffing and Facility as published by the Tennessee Department of Health, Division of Family Health and Wellness. The Tennessee Perinatal Care System, Guidelines for Regionalization, Hospital Care Levels, Staffing and Facility shall be published by reference on the Health Facilities Commission website.

(b) Levels of Care – Neonatal Intensive Care Units II-IV Requirements:

1. Facility Capacity

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | Provide care for infants born at >32 weeks' gestation and weighing >1500 grams who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis. | E | E | E |
| (ii) | Provide mechanical ventilation for brief duration (<24 hours) and provide continuous positive airway pressure (CPAP). | E | E | E |
| (iii) | Stabilize infants born at <32 weeks' gestation and weighing <1500 grams until transfer to a neonatal intensive care facility. | E | E | E |
| (iv) | Provide care for infants who are convalescing after intensive care. | E | E | E |
| (v) | Provide sustained life support. | E | E | |
| (vi) | Provide comprehensive care for infants born <32 weeks gestation and weighing <1500 grams and infants born at all gestational ages and birth weights with critical illness. | E | E | |
| (vii) | Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists. | E | E | |
| (viii) | Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide. | E | E | |
| (ix) | Perform advanced imaging with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography. | E | E | |

| | | | | |
|---|---|---|---|---|
| (x) | Perform advanced imaging with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography. | E | E | |
| (xi) | Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions. | E | | |
| (xii) | Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site. | E | | |
| (xiii) | Facilitate transport. | | | |

2. Education Services

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Educational services should include the following:** | | | |
| | All neonatal care providers should maintain both current NRP and S.T.A.B.L.E. provider status. The S.T.A.B.L.E. Cardiac Module is also recommended. | E | E | E |
| (ii) | **Parent Education** | | | |
| | Ongoing perinatal education programs for parents. | E | E | E |
| (iii) | **Nurses' Education** | | | |
| | Required to provide ongoing educational programs for their nurses that conform to the latest edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level IV, for neonatal nurses, published by the Tennessee Department of Health. Outreach educational activities are not required. | E | | |
| | Required to provide ongoing educational programs for their nurses that conform to the latest edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level III, for neonatal nurses, published by the Tennessee Department of Health. Outreach educational activities are not required. | | E | |
| | Programs for nurses that conform to the latest edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level II, for neonatal nurses, published by the Tennessee Department of Health. These neonatal courses should be made available periodically at Level II facilities by instructors on the staff of that institution and/or the staff from a Regional Perinatal Center. Courses may also transpire at a Regional Perinatal Center or at another site remote from the Level II hospital, thus requiring that the hospital provide nurses with educational leave for attendance. Level II hospitals are responsible for the necessary arrangements for nurse education. | | | E |
| (iv) | **Physicians' Education** | | | |
| | [redacted] required. | E | E | |
| | [redacted] | E | | |
| | For the Staff of Other Hospitals in the Region: The Regional Perinatal Center must maintain a program of professional outreach education for hospitals within its region. These programs of instruction require a staff of qualified educators to present ongoing courses to Level I, II, and III hospitals. These courses must satisfy the educational objectives set forth in the series of publications for the education of nurses and social workers published by the Tennessee Department of Health. | E | | |
| | Educational opportunities for physicians should be available upon request, provided by the instructional staff of the Regional Perinatal Center and by qualified individuals on the staff of the Level II institution. | | | E |
| (v) | **Site Visits** | | | |
| | The Regional Perinatal Center staff will engage in site visits upon request within its region. | E | | |

3. Neonatal Care

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Resuscitation** | | | |
| | Provision must be made for resuscitation of infants immediately after birth. Resuscitation capabilities should include assisted ventilation with blended oxygen administered by bag or T-piece resuscitator with mask or endotracheal tube, chest compression, and appropriate intravascular therapy. Refer to the most recent edition of the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program Guidelines for a complete list of resuscitation equipment and supplies. | E | E | |
| (ii) | **Transport from Delivery Room to the Special Care Nursery** | | | |
| | Transport to a special care nursery requires a capacity for uninterrupted support. An appropriately equipped pre-warmed transport incubator, with blended oxygen, should be used for this purpose. | E | E | |
| (iii) | **Transitional Care** | | | |
| | Recurrent observation of the neonate should be performed by personnel who can identify and respond to the early manifestations of neonatal disorders. | E | E | |
| (iv) | **Care of Sick Neonates** | | | |
| (I) | The care of moderately and severely ill infants entails the following essentials: | | | |
| | Continuous cardiorespiratory monitoring. | E | E | |
| | Serial blood gas determinations and non-invasive blood gas monitoring. | E | E | |
| | Periodic blood pressure determinations (intra-arterial when necessary). | E | E | |
| | Portable diagnostic imaging for bedside interpretation. | E | E | |
| | Availability of electrocardiograms and echocardiograms with rapid interpretation. | E | E | |
| | Laboratory Services: Clinical laboratory services must be available to fully support clinical neonatal functions. | E | E | |
| | Fluid and electrolyte management and administration of blood and blood components. | E | E | |
| | Phototherapy and exchange transfusion. | E | E | |
| | Administration of parenteral nutrition through peripheral or central vessels. | E | E | |
| | [redacted] | | | |
| (v) | **Mechanical Ventilatory Support** | | | |
| (I) | Unit must be qualified to provide mechanical ventilatory support. The essential qualifications are as follows: | | | |
| | Continuous in-house presence of personnel experienced in airway management, endotracheal intubation, and diagnosis and treatment of air leak syndromes. | E | E | |
| | A staff of nurses (R.N.) and respiratory therapists (R.T.) who are specifically educated in the management of neonatal respiratory disorders. | E | E | |
| | Blood gas determinations and other data essential to treatment must be available 24 hours a day, 7 days a week. | E | E | |
| | Level III nurseries should be able to provide a full range of respiratory support, including sustained conventional and/or high frequency ventilation and inhaled nitric oxide. | E | E | |
| (vi) | **Diagnostic Imaging** | | | |
| | Perform advanced imaging, with interpretation on an urgent basis, including CT, MRI, and echocardiography. | E | E | |
| (vii) | **Laboratory Services** | | | |
| | [redacted] | E | E | |
| (viii) | **Transfusion Services** | | | |
| | Transfusion services must be maintained at all times. | | | |
| | An appropriately trained technician should be available in-house 24 hours a day, 7 days a week. | E | E | |

| | | | | |
|---|---|---|---|---|
| | All blood components must be obtainable on an emergency basis from within the facility. | E | | |
| | All blood components must be obtainable on an emergency basis, either on the premises or by pre-arrangement with another facility. | | E | |
| | Transfusion services should be maintained at all times. An appropriately trained technician should be in-house 24 hours a day, 7 days a week. All blood components must be available on an emergency basis, either on the premises or by pre-arrangement with another facility. | | | E |

4. Ancillary Services

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Laboratory Services:** | | | |
| |  | E | E | |
| (I) | Laboratory capabilities should include but not be limited to the following: | | | |
| I. | **Routine Availability** | | | |
| | Clotting factors | E | E | E |
| | Serum total protein | E | E | E |
| | Serum total protein | E | E | E |
| | Serum albumin | E | E | E |
| | Serum IgM | E | E | E |
| | Serum triglycerides (for parenteral nutrition) | E | E | E |
| | Metabolic screen | E | E | E |
| | Liver function tests | E | E | E |
| | Serologic test for syphilis | E | E | E |
| | Serology for hepatitis | E | E | E |
| | Screening for HIV | E | E | E |
| | TORCH titers | E | E | E |
| | Viral cultures | E | E | E |
| II. | **Available 24 Hours - 7 Days a Week** | | | |
| | Hematocrit | E | E | E |
| | Hemoglobin | E | E | E |
| | Complete blood count | E | E | E |
| | Reticulocyte count | E | E | E |
| | Blood typing: major groups and Rh | E | E | E |
| | Cross match | E | E | E |
| | Minor blood group antibody screen | E | E | E |
| | Coombs' test | E | E | E |
| | Prothrombin time | E | E | E |
| | Partial thromboplastin time | E | E | E |
| | Platelet count | E | E | E |
| | Fibrinogen concentration | E | E | E |
| | Serum sodium, potassium, chloride | E | E | E |
| | Serum calcium | E | E | E |
| | Serum phosphorus | E | E | E |
| | Serum magnesium | E | E | E |
| | Serum blood glucose | E | E | E |
| | Therapeutic drug levels | E | E | E |
| | Serum bilirubin, total and direct | E | E | E |
| | Blood gases/pH | E | E | E |
| | Blood urea nitrogen | E | E | E |
| | Serum creatinine | E | E | E |
| | Serum/urine osmolalities | E | E | E |
| | Urinalysis | E | E | E |
| | Cerebrospinal fluid: cells, chemistry | E | E | E |

| | | | | |
|---|---|---|---|---|
| | Bacterial cultures and sensitivities | E | E | E |
| | C-reactive protein (CRP) | E | E | E |
| | Gram stain | E | E | E |
| | Toxicology | E | E | E |
| | Group B strep screening | E | E | E |

5. Consultation and Transfer

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Neonatal Transport:** | | | |
| | The Level IV facility that operates a transport service is required to maintain equipment and a trained team of personnel for the transport of newborn patients. The team and equipment must be available at all times. The Level IV facility is responsible for transport of referred infants with its own equipment, or alternatively, with equipment from a commercial source. | E | E | |
| | The Level IV facility that operates a transport service should originate a protocol that describes procedures, staffing patterns, and equipment for the transport of referred infants. The protocol should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health. | E | E | |
| | The Level IV facility that operates a transport service is required to maintain records of its activities. (See the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation.) | E | E | |
| | The Level II facility should maintain an active relationship with a Level III or Level IV facility in the region for consultation and transfer. Protocols for transport should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health. | | | E |
| | Neonatal Consultation and Transport: When the severity of an illness requires a level of care that exceeds the capacity of the Level II facility, the infant should be transferred to a Level III or Level IV institution capable of providing required care. Transfer of these infants should be provided after consultation with the receiving Level III or Level IV unit. Refer to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health, for more information. | | | E |
| (ii) | **Maternal-Fetal and Neonatal Transport** | | | |
| | The Regional Perinatal Center is responsible for maternal-fetal and neonatal transport described for Level III or Level IV facilities elsewhere in these Guidelines. Whereas the provision of these transport services is an option for Level III or Level IV units that do not function as Regional Perinatal Centers, transport services are required of a Regional Perinatal Center. Transport for the purpose of admission to the Regional Center must be made available to all patients within the state regardless of their financial status, and to patients referred from other Regional Perinatal Centers. Protocols for transport should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health. | E | | |
| | If no other appropriate facility is available to manage significant high-risk conditions, the Regional Perinatal Center must accept all such patients regardless of financial status. | E | | |
| | [redacted] physicians and nurses within the region 24 hours a day. | E | | |

6. Maintenance of Data

| | Requirement | IV | III | II |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| (i) | **Maintenance of Data and Assessment of Quality Measures** | | | |
| (I) | The following items represent the minimum information that should be in medical records maintained at Level I facilities: | | | |
| | Name, gender, hospital medical record number | E | E | E |
| | Date of birth | E | E | E |
| | Birthweight | E | E | E |
| | Gestational age | E | E | E |
| | Apgar scores | E | E | E |
| | Maternal complications (test results relevant to neonatal care; maternal illness potentially affecting the fetus; history of illicit substance use or any other known socially high-risk circumstances; complications of pregnancy associated with abnormal fetal growth, fetal anomalies, or abnormal results from tests of fetal well-being; information regarding labor and delivery; and situations in which lactation may be compromised) | E | E | E |
| | Discharge diagnoses | E | E | E |
| | Special care administered (specify) | E | E | E |
| | Documentation of newborn metabolic, hearing and critical congenital heart disease (CCHD) screens, and immunizations and medications given | E | E | E |
| | Bilirubin screen (according to American Academy of Pediatrics guidelines) | E | E | E |
| | Disposition<br>-Discharged home<br>-Transferred to a higher level of care / Receiving hospital / Transport service<br>-Expired | E | E | E |
| (II) | A systematic ongoing compilation of data should be maintained to reflect the care of sick patients, in addition to the listing of minimal data that is specified | E | E | |
| (ii) | **Data Collection** | | | |
| | The Regional Perinatal Center must compile data (Program Objectives Report [POR]) on educational outreach that is performed as well as the region's analysis and evaluation of maternal and neonatal outcomes for quality improvement according to requirements prescribed by the Tennessee Perinatal Care System. These data are forwarded to a central facility on a regular basis. All Regional Perinatal Centers, if possible, should support clinical teams within the institution that are responsible for implementing State or National continuous quality improvement initiatives by providing advisory assistance, sharing data from the POR, disseminating information to the region, and/or aiding with financial support. | E | | |

7. Personnel Qualifications and Functions

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Physicians** | | | |
| (I) | **Director** | | | |
| | The director of the newborn intensive care unit must be a full-time, board-certified pediatrician with subspecialty certification in neonatal-perinatal medicine. The director is responsible for maintaining practice guidelines and, in cooperation with nursing and hospital administration, is responsible for developing the operating budget; evaluating and purchasing equipment; planning, developing, and coordinating in-hospital and outreach educational programs; and participating in the evaluation of perinatal care. | E | E | |
| | In a Level II hospital, a board-certified pediatrician with subspecialty certification in neonatal-perinatal medicine should be chief of the neonatal care service. The chief should assure that appropriate trained and adequate staff | | | E |

| | | | | |
|---|---|---|---|---|
| | are available at all times. | | | |
| (II) | **Neonatologists** | | | |
| | The attending physician for [redacted] must be fellowship-trained and board-certified or eligible to take the board certification exam in neonatal-perinatal medicine. | E | E | |
| | The co-directors of perinatal services should coordinate the hospital's perinatal care services and, in conjunction with other medical, anesthesia, nursing, respiratory therapy, and hospital administration staff, develop policies concerning staffing, procedures, equipment, and supplies. The medical directors of obstetrics and neonatology are responsible for setting the hospital's standard of perinatal care by working together to incorporate evidence-based practice patterns and nationally recognized care standards. | | | E |
| (III) | **Pediatricians** | | | |
| | A board-certified neonatologist must have primary and ultimate responsibility for infants who receive intensive care. Board-certified pediatricians, whose qualifications and appointments have been approved by the appropriate hospital committee, can care for infants who need more than routine care as long as they are under the supervision of a neonatologist. | E | E | |
| (IV) | **In-House Coverage** | | | |
| | In-house physician consultation and coverage should be provided 24 hours a day, 7 days a week by a board-certified neonatologist or a board-certified neonatal nurse practitioner. However, when in-house coverage does not include a board-certified neonatologist, he/she must be on-call and available to be on-site within 30 minutes of request. | E | E | |
| (V) | **Deliveries** | | | |
| | Deliveries of high-risk fetuses should be attended by an obstetrician and at least two other persons qualified in neonatal resuscitation whose only responsibility is the neonate. With multiple gestations, each newborn should have his or her own dedicated team of care providers who are capable of performing neonatal resuscitation according to the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program guidelines. | | | E |
| | Every delivery should be attended by at least one person whose primary responsibility is for the newborn and who is capable of performing neonatal resuscitation according to the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program guidelines. Either that person or someone else who is immediately available should have the skills required to perform a complete resuscitation, including endotracheal intubation and administration of medications. | E | E | E |
| | Deliveries of high-risk fetuses should be attended by an obstetrician and at least two other persons qualified in neonatal resuscitation whose only responsibility is the neonate. With multiple gestations, each newborn should have his or her own dedicated team of care providers who are capable of performing complete neonatal resuscitation according to the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program guidelines. | E | E | |
| (VI) | **Anesthesiologists** | | | |
| | Pediatric anesthesia services should be directed by a board-certified anesthesiologist who has a special interest and an expertise in pediatric anesthesia. | E | E | |
| (VII) | **Radiologists** | | | |
| | A radiologist must be available on-call at all times. | E | E | |
| (VIII) | **Sub-specialty Consultants** | | | |
| | Should have pediatric surgical sub-specialists on call and readily available for consultation and continuous patient management. | E | | |
| | Should be available on-site or at a closely related institution by prearranged consultative agreement, ideally in close geographic proximity. | | E | |

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| | Pediatric medical subspecialists | E | E | |
| | Pediatric surgical specialists | E | E | |
| | Pediatric anesthesiologists | E | E | |
| | Pediatric ophthalmologists | E | E | |
| (ii) | **Nurses** | | | |
| (I) | **The Nurse Manager** | | | |
| | Of the Level IV nursery should have completed education according to the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level IV, Neonatal, published by the Tennessee Department of Health. A baccalaureate degree is required. | E | | |
| | Of the Level III nursery should have completed education according to the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level III, Neonatal, published by the Tennessee Department of Health. A baccalaureate degree is required. | | E | |
| | The nurse manager (R.N.) is responsible for all nursing activities in the nurseries of Level II facilities. The nurse manager in a hospital with a Level II nursery must complete the Level II neonatal courses prescribed for staff nurses in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level II, published by the Tennessee Department of Health. | | | E |
| (II) | **Staff nurses (R.N.)** | | | |
| | Must have received courses as outlined in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level IV, for neonatal nurses, published by the Tennessee Department of Health. Nurses should maintain institutional unit-specific competencies. In addition, all nurses should be current NRP and S.T.A.B.L.E. providers. | E | | |
| | Must have received courses as outlined in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level III, for neonatal nurses, published by the Tennessee Department of Health. Nurses should maintain institutional unit-specific competencies. In addition, all nurses should be current NRP and S.T.A.B.L.E. providers. | | E | |
| | Must be skilled in the observation and treatment of sick infants. For Level II facilities, they must complete the Level II neonatal course for nurses outlined in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, published by the Tennessee Department of Health. Nurses should maintain institutional unit-specific competencies. In addition, all nurses should be current NRP and S.T.A.B.L.E. providers. | | | E |
| (III) | **Nurse Educator** | | | |
| | Should have at least one neonatal nurse on its full-time staff who is responsible for staff education. This nurse should either be masters' prepared or actively pursuing an advanced degree. | E | E | |
| (IV) | **Recommended Registered Nurse (R.N.) / Patient Ratios for Newborn Care (Association of Women's Health, Obstetric, and Neonatal Nurses Guidelines for Professional Registered Nurse Staffing for Perinatal Units, 2010):** | | | |
| | 1:5-6 Newborns requiring only routine care | | | E |
| | 1:3-4 Newborns requiring continuing care | | | E |
| | 1:2-3 Newborns requiring intermediate care | E | E | E |
| | 1:1-2 Newborns requiring intensive care | E | E | E |
| | 1:1 Newborns requiring multisystem support | E | E | E |
| | 1 or more :1 Unstable newborns requiring complex critical care | E | E | E |
| (iii) | **Social Workers** | | | |
| | The services of social workers should be made available by the hospital 24 hours a day, 7 days a week. These services should be provided by a staff that is qualified in perinatal social work. This requires that social workers be educated according to the most recent edition of the Tennessee Perinatal Care System Educational Objectives in Medicine for Perinatal Social Workers, | E | E | |

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| | published by the Tennessee Department of Health. | | | |
| (iv) | **Case Manager / Discharge Coordinator** | | | |
| (I) | **Case Manager / Discharge Coordinator** | | | |
| | Personnel experienced in dealing with discharge planning and education, follow-up and referral, and home care planning should be available to neonatal intensive care unit staff members and families. | E | E | |
| | Personnel experienced in dealing with perinatal issues, discharge planning and education, follow-up and referral, home care planning, and bereavement support should be available to intermediate and intensive care unit staff members and families. | | | E |
| (II) | **Post-discharge Maternal Follow-up** | | | |
| | Follow-up evaluation of selected women who are discharged from the Regional Perinatal Center should be arranged. | E | | |
| (III) | **Post-discharge Neonatal Follow-up** | | | |
| | Follow-up evaluation of selected infants who are discharged from the Regional Perinatal Center should be performed. Neonatal intensive care unit graduates who are considered high risk and those with birthweights <1500 grams should be enrolled in an organized follow-up program that tracks and records medical and neurodevelopmental outcomes to allow later analysis. | E | | |
| (v) | **Respiratory Therapists** | | | |
| | Respiratory therapists who can provide supplemental oxygen, assisted ventilation and continuous positive pressure ventilation (including high flow nasal cannula) of neonates with cardiopulmonary disease should be continuously available on-site to provide ongoing care as well as to address emergencies. | | | E |
| | Dedicated respiratory therapists who can provide the assisted ventilation of neonates with cardiopulmonary disease must be available. The nursery's respiratory therapy director must be a registered respiratory therapist (R.R.T.). | E | E | |
| (vi) | **Dietitian / Lactation Consultant** | | | |
| | The staff must include at least one dietitian who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk neonates. Availability of lactation consultants 7 days a week is recommended to assist with complex breastfeeding issues. 1.6 full-time equivalent lactation consultants are recommended for every 1,000 births based on annual birth volume in Level II perinatal facilities (Association of Women's Health, Obstetric, and Neonatal Nurses Guidelines for Professional Registered Nurse Staffing for Perinatal Units, 2010). | | | E |
| | The staff must include at least one dietitian who is knowledgeable in the management of parenteral and enteral nutrition of low birthweight and other high-risk infants. Availability of lactation consultants 7 days a week is recommended to assist with complex breastfeeding issues. 1.9 full-time equivalent lactation consultants are recommended for every 1,000 births based on annual birth volume in Level III (also applies to Level IV) perinatal facilities (Association of Women's Health, Obstetric, and Neonatal Nurses Guidelines for Professional Registered Nurse Staffing for Perinatal Units, 2010). | E | E | |
| (vii) | **Pharmacist** | | | |
| | A registered pharmacist with expertise in compounding and dispensing medications, including total parenteral nutrition (TPN) for neonates must be available 24 hours a day, 7 days a week. | | | E |
| | A registered pharmacist with expertise in compounding and dispensing medications for neonates must be included on staff. Registered pharmacists with expertise in dispensing neonatal medications, including total parenteral nutrition (TPN), must be available 24 hours a day, 7 days a week. | E | E | |
| (viii) | **Occupational Therapist / Physical Therapist / Speech Therapist** | | | |
| | At least one occupational therapist or physical therapist and one speech | E | E | |

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| | therapist with neonatal expertise must be included on staff. These disciplines will work collaboratively with the medical and nursing staffs to provide developmentally appropriate care. | | | |
| (ix) | **Neonatal Follow-up Services** | | | |
| | Neonatal intensive care unit graduates who are considered high risk and those with birthweights <1500 grams should be enrolled in an organized follow-up program that tracks and records medical and neurodevelopmental outcomes to allow later analysis. | E | E | |

8. Space and equipment for level II Facilities

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Physical facilities and equipment** | | | |
| | Physical facilities and equipment should meet criteria published in the latest edition of the Guidelines for Perinatal Care, jointly published by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. | | | E |
| | Equipment in the intensive care nursery of a Level III or IV facility should be adequate for the care of moderately and severely ill infants in accordance with contemporary standards. The quantities of all items of equipment should be sufficient to support the management of the maximum number of infants that are anticipated at times of peak census loads. An in-house Bioengineering Department should have an active program for preventive maintenance and rapid repair. | E | E | |
| (ii) | **Minimal equipment for care of the normal infant includes:** | | | |
| (II) | **Minimal equipment for care of the normal infant includes:** | | | |
| | A platform scale, preferably with metric indicators. | E | E | E |
| | A controlled source of continuous and/or intermittent suction. | E | E | E |
| | Incubators and/or radiant warmers for adequate thermal support. | E | E | E |
| | Equipment for determination of blood glucose at the bedside. | E | E | E |
| | Ability to provide intensive phototherapy. | E | E | E |
| | A device for the external measurement of blood pressure from the infant's arm or thigh. | E | E | E |
| | Oxygen flow meters, tubing, binasal cannulas for short-term administration of oxygen. | E | E | E |
| | A headbox assembly (oxygen hood), an oxygen blending device, and warming nebulizer for short-term administration of oxygen. | E | E | E |
| | An oxygen analyzer that displays the ambient concentration of oxygen. | E | E | E |
| | A newborn pulse oximeter for non-invasive blood oxygen monitoring. | E | E | E |
| | An infusion pump that can deliver appropriate volumes of continuous fluids and/or medications for newborns. | E | E | E |
| | A fully equipped neonatal resuscitation cart. | E | E | E |
| | Positive pressure ventilation equipment and masks; endotracheal tubes in all the appropriate sizes for neonates. | E | E | E |
| | A laryngoscope with premature and infant size blades. | E | E | E |
| | A CO2 detector. | E | E | E |
| | Laryngeal mask airway (LMA, size 1) | E | E | E |
| (II) | **Intermediate Care Nursery** | | | |
| | Additional equipment needed for intermediate care newborns includes: | E | E | E |
| | A servo-controlled incubator or heated open bed for each infant who requires a controlled thermal environment. | E | E | E |
| | Cardiorespiratory monitors that include pressure and waveform monitoring. | E | E | E |
| | Oxygen analyzers, blenders, heaters, and humidifiers sufficient for anticipated census. | E | E | E |
| | A sufficient number of headbox assemblies (oxygen hoods). | E | E | E |
| | Modes of respiratory support: binasal cannulas, conventional mechanical ventilator, mechanism to deliver nasal CPAP. | E | E | E |

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| | A bag or t-piece resuscitator and mask for each infant. | E | E | E |
| | An adequate supply of endotracheal tubes and other intubation supplies and LMA. | E | E | E |
| | A device for viewing x-rays in the infant area. | E | E | E |

(c) If a hospital provides NICU services the following administrative requirements apply:

1. The NICU must have a NICU Director who is responsible for the following:

(i) All NICU administrative functions;

(ii) Creation of policies and procedures regarding NICU care;

(iii) Ensure NICU staff are properly credentialed through the general hospital's medical staff credentialing process; and

(iv) Any other requirements in 0720-48-.02.

2. The NICU must have a Nurse Manager who is responsible for all NICU nursing functions.

(d) A NICU patient qualifying for lvl III care may be able to receive lvl II care services and continue as a patient if the patient's treating physician certifies that such care can be appropriately provided in the lvl II NICU.

(17) PET Services

(a) If a hospital provides PET services, the following licensing requirements apply:

1. Each PET unit must become accredited by a nationally recognized and CMS approved accrediting organization within one year of licensure per machine and per diagnostic type.

(b) All PET units must adhere to all federal and state regulations.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-209, 68-57-101, 68-57-102, 68-57-104, and 68-57-105.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed June 12, 2003; effective August 26, 2003. Amendment filed July 27, 2005; effective October 10, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendments filed July 10, 2018; effective October 8, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.08 BUILDING STANDARDS.**

(1) A hospital shall construct, arrange, and maintain the condition of the physical plant and the overall hospital environment in such a manner that the safety and well-being of the patients are assured.

~~(2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including~~

~~referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.~~

(2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the Commission. All facilities shall conform to the current edition of the following applicable codes as approved by the Commission: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.

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

(4) A licensed contractor shall perform all new construction and renovations to hospitals, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in hospitals, including the submission of phased construction plans and the final drawings and the specifications to each.

~~(5) No new hospital shall be constructed, nor shall major alterations be made to an existing hospital without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new hospital is licensed or before any alteration or expansion of a licensed hospital can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.~~

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

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

~~(7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the department requires.~~

(7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the Commission may require. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the Commission requires.

~~(a) The project architect or engineer shall forward two (2) sets of plans to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the owner's understanding that such work is at the owner's own risk and without assurance that final approval of final plans and specifications shall be granted. The project architect or engineer shall submit final plans and specifications for review and approval. The department must grant final approval before the project proceeds beyond foundation work.~~

(a) The project architect or engineer shall forward two (2) sets of plans to the Commission for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the owner's understanding that such work is at the owner's own risk and without assurance that final approval of final plans and specifications shall be granted. The project architect or engineer shall submit final plans and specifications for review and approval. The commission must grant final approval before the project proceeds beyond foundation work.

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

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

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

(10) Architectural drawings shall include where applicable:

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

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

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

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

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

(j) Code analysis.

(11) Structural drawings shall include where applicable:

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

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

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

(12) Mechanical drawings shall include where applicable:

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

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

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

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

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

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

(13) Electrical drawings shall include where applicable:

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

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

(c) An electrical system that complies with applicable codes;

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

(e) Circuit breakers that are properly labeled; and

(f) Ground-Fault Circuit Interrupters (GFCI) that are required in all wet areas, such as kitchens, laundries, janitor closets, bath and toilet rooms, etc, and within six (6) feet of any lavatory.

(14) The electrical drawings shall not include knob and tube wiring, shall not include electrical cords that have splices, and shall not show that the electrical system is overloaded.

(15) In all new facilities or renovations to existing electrical systems, the installation must be approved by an inspector or agency authorized by the State Fire Marshal.

(16) Sprinkler drawings shall include where applicable:

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

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

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

~~(17) The licensed contractor shall not install a system of water supply, plumbing, sewage, garbage or refuse disposal nor materially alter or extend any existing system until the architect or engineer submits complete plans and specifications for the installation, alteration or extension, to the department demonstrating that all applicable codes have been met and the department has granted necessary approval.~~

(17) The licensed contractor shall not install a system of water supply, plumbing, sewage, garbage or refuse disposal nor materially alter or extend any existing system until the architect or engineer submits complete plans and specifications for the installation, alteration or extension, to the Commission demonstrating that all applicable codes have been met and the Commission has granted necessary approval.

(a) Before the hospital is used, Tennessee Department of Environment and Conservation shall approve the water supply system.

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

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

(18) It shall be demonstrated through the submission of plans and specifications that in each hospital:

(a) 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;

(b) Rooms and areas containing radiation producing machines or radioactive material must have primary and/or secondary barriers to assure compliance with Regulations for Protection Against Radiation and security for materials. Radiation material shall be required to be stored and security must be provided in accordance with federal and state regulations to prevent exposure of the material to theft or tampering.

(19) When constructing new facilities or during major renovations to the operating suites, the hospital shall ensure that male and female physicians and staff have equitable proportional locker facilities including equal equipment, and similar amenities, with equal access to uniforms. Existing hospitals shall strive to have equitable male and female facilities. If physical changes are required, the additional areas shall maintain the flow and divisions in the sterile environments.

~~(20) The department shall acknowledge that it has reviewed plans and specifications in writing with copies sent to the project architect, the project engineer, the owner, the manager or other executive of the institution. The department may modify the distribution of such review at its discretion.~~

(20) The Commission shall acknowledge that it has reviewed plans and specifications in writing with copies sent to the project architect, the project engineer, the owner, the manager or other

executive of the institution. The Commission may modify the distribution of such review at its discretion.

~~(21) In the event submitted materials do not appear to satisfactorily comply with 0720-14-.08(2), the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.~~

(21) In the event submitted materials do not appear to satisfactorily comply with 0720-14-.08(2), the Commission 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.

(22) The licensed contractor shall execute all construction in accordance with the approved plans and specifications

~~(23) If construction begins within one hundred eighty (180) days of the date of department approval, the department's written notification of satisfactory review constitutes compliance with 0720-14-.08(2). This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.~~

(23) If construction begins within one hundred eighty (180) days of the date of Commission approval, the Commission's written notification of satisfactory review constitutes compliance with 0720-14-.08(2). This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

~~(24) Prior to final inspection a CD Rom disc, in TIF or PDF format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.~~

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

~~(25) The department requires the following alarms that shall be monitored twenty-four (24) hours per day:~~

(25) The Commission requires the following alarms that shall be monitored twenty-four (24) hours per day:

(a) Fire alarms;

(b) Generators (if applicable); and

(c) Medical gas alarms (if applicable).

(26) Each hospital shall ensure that an emergency keyed lock box is installed next to each bank of functioning elevators located on the main level. Such lock boxes shall be permanently mounted seventy-two inches (72") from the floor to the center of the box, be operable by a universal key no matter where such box is located, and shall contain only fire service keys and drop keys to the appropriate elevators.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 68-11-261.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed February 18, 2003; effective May 4, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007. Repeal and new rule*

*filed December 20, 2011; effective March 19, 2012. Amendment filed January 21, 2016; effective April 20, 2016. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.09 LIFE SAFETY.**

~~(1) Any hospital 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.~~

(1) Any hospital 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 hospital 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. Fire drills shall be held at least quarterly for each work shift for hospital personnel in each separate patient-occupied hospital building. There shall be a written report documenting the evaluation of each drill and the action recommended or taken for any deficiencies found. Records which document and evaluate these drills must be maintained for at least three (3) years. 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.~~

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***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendments filed September 6, 2005; effective November 20, 2005. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.10 INFECTIOUS WASTE AND HAZARDOUS WASTE.**

(1) Each hospital 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, waste from the production of biologicals, discarded live and attenuated vaccines, 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 surgery and autopsy;

(e) All discarded sharps (e.g., 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; and

(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 storage, 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 or stored 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 disinfected each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable fluid resistant liners or other devices removed with the waste; and

(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) Infectious 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; and

(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.

(c) Outside containers should have a biohazard label conspicuously identified.

(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 waste 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 waste shall be stored, transported, and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily cleanable material and shall be kept on elevated platforms.

***Authority:*** *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.11 RECORDS AND REPORTS.**

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

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

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

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

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

(b) An Acknowledgment of Paternity Form provided by the Tennessee Department of Health; and

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

~~(4) A report of fetal death shall be completed by the hospital for each dead fetus delivered where the fetus weighs three hundred fifty (350) grams or more, or in the absence of weight, is of~~

~~twenty (20) completed weeks of gestation or more. The report shall be in a form or format approved by the State Registrar and shall be submitted to the department's Office of Vital Records within ten (10) days of the delivery.~~

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

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

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

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

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

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

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

(8) The hospital shall report all incidents of abuse, neglect, and misappropriation to the

Commission in accordance with T.C.A. § 68-11-211.

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

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

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

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

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

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

(11) The hospital shall report, at least quarterly to the Commission, claims data on the UB-04 form or its successor for all discharges from the facility.

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

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

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

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

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

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

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

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

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

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

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

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

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

(g) Orders of the Commission, if any;

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

(i) Maintenance records of all safety equipment.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-3-102, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-310.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007. Amendments filed January 3, 2012; effective April 2, 2012. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.12 PATIENT RIGHTS.**

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

(a) To privacy in treatment and personal care;

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

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

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

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

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

maker. The hospital must have policies to govern access and duplication of the patient's record;

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

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

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

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

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendments filed September 6, 2005; effective November 20, 2005. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.**

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

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

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

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

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

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the 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) 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 0720-14-.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 0720-14-.13(16)(c) through 0720-14-.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 0720-14-.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 0720-14-.13(20) through 0720-14-.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 0720-14-.13(20) through 0720-14-.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) Physician Orders for Scope of Treatment (POST)

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

1. With the informed consent of the patient;

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

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

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

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

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

3. Either:

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

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

4. Either:

(i) With the informed consent of the patient;

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

(iii) If the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act, is not reasonably available and such authority to issue is contained in the physician assistant, nurse practitioner or clinical nurse specialist's protocols and the physician assistant or nurse determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

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

~~(d) A POST issued in accordance with this section shall remain valid and in effect until revoked in accordance with this rule and applicable regulations, qualified emergency medical services personnel; and licensed health care practitioners in any facility, program, or organization operated or licensed by the Board for Licensing Health Care Facilities, the Department of Mental Health and Substance Abuse Services, or the Department of Intellectual and Developmental Disabilities, or operated, licensed, or owned by another state agency, shall follow a POST that is available to such persons in a form approved by the Board for Licensing Health Care Facilities~~

(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

(Rule 0720-14-.15, continued)

arrest in accordance with accepted medical practices. This action shall have no application to any do-not-resuscitate order that is not a POST, as defined in these rules.

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

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-224, and 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 7, 2007; effective April 23, 2007. Amendments filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.14 DISASTER PREPAREDNESS.**

(1) Emergency Electrical Power.

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

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

(c) The emergency power system shall have a minimum of twenty-four (24) hours of either propane, natural gas, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the hospital shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month. Records shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every hospital shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills.

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients to other health care facilities must have written agreements for emergency transfers. Their agreements may be mutual, i.e. providing for transfers either way.

(Rule 0720-14-.15, continued)

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to all staff. Provisions that have security implications may be omitted from the outline versions. Familiarization information shall be included in employee orientation sessions and more detailed instructions must be included in continuing education programs. Records of orientation and education programs must be maintained for at least three (3) years.

4. Drills of the disaster preparedness plan shall be conducted at least once a year. The risk focus may vary by type of drill. Drills are for the purpose of educating staff, resource determination, testing personal safety provisions and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

5. As soon as possible, real situations that result in a response by local authorities must be documented. This includes a critique of the activation of the plan. Actual documented situations that had education and training value may be substituted for a drill.

(b) Community Emergency (Mass Casualty).

1. Every hospital, unless exempted due to its limited scope of clinical services, shall have a plan that provides for the reception and treatment, within its capabilities, of medical emergencies resulting from a disaster within its usual service area. The plan should consider the probability of the types of disasters which might occur, both natural and “man-made”.

2. The plan must provide for additional staffing, medical supplies, blood and other resources which would probably be needed. The plan must also include for the deferral of elective admission patients and also for the early transfer or discharge of some current patients if it appears that the number of casualties will exceed available staffed beds.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to staff who would be assigned non-routine duties during these types of emergencies. Familiarization information shall be included in employee orientation sessions and more detailed instruction must be included in continuing education programs. Records of orientation and education must be maintained for at least three (3) years.

4. At least one drill shall be conducted each year for the purpose of educating staff, resource determination, and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

5. As soon as possible, actual community emergency situations that result in the treatment of more than twenty (20) patients, or fifteen percent (15%) of the licensed bed capacity, whichever is less, must be documented. Actual situations that had education and training value may be substituted for a drill. This includes documented actual plan activation during community emergencies, even if no patients are received.

(c) Emergency Planning with Local Government Authorities.

1. All hospitals shall establish and maintain communications with the county

(Rule 0720-14-.15, continued)

Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The facility shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

2. Each hospital must rehearse both the Physical Facility and Community Emergency plan as required in these regulations, even if the local Emergency Management Agency is unable to participate.

3. A file of documents demonstrating communications and cooperation with the local agency must be maintained.

***Authority:*** *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.15 APPENDIX I**

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

| | |
|---|---|
| Tennessee Physician Orders for Scope of Treatment<br>(POST, sometimes called "POLST")<br><br>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<br><br>First Name/Middle Initial<br><br>Date of Birth |

| | |
|---|---|
| **Section A**<br>*Check One Box Only* | **CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse and is not breathing.**<br>☐ **Resuscitate(CPR)** ☐ **Do Not Attempt Resuscitation (DNR / no CPR) (Allow Natural Death)**<br>When not in cardiopulmonary arrest, follow orders in **B, C,** and **D.** |
| **Section B**<br><br>*Check One Box Only* | **MEDICAL INTERVENTIONS. Patient has pulse and/or is breathing.**<br><br>☐ **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.**<br><br>☐ **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.**<br><br>☐ **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.**<br><br>*Other Instructions:*_____ |
| **Section C**<br>*Check One* | **ARTIFICIALLY ADMINISTERED NUTRITION. Oral fluids & nutrition must be offered if feasible.**<br>☐ No artificial nutrition by tube.<br>☐ Defined trial period of artificial nutrition by tube.<br>☐ Long-term artificial nutrition by tube.<br><br>*Other Instructions:*_____ |

(Rule 0720-14-.15, continued)

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

| **Physician/NP/CNS/PA Name (Print)** | **Physician/NP/CNS/PA Signature Date**<br><br>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 |
| | | | |

(Rule 0720-14-.15, continued)

**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.

(Rule 0720-14-.15, continued)

(2) Advance Directive for Health Care Form.

**ADVANCE DIRECTIVE FOR HEALTH CARE***
(Tennessee)

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

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

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

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

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

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

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

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

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

| | |
|---|---|
| ☐ 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. |

(Rule 0720-14-.15, continued)

| | |
|---|---|
| ☐ 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

(Rule 0720-14-.15, continued)
is personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who signed as the "patient." The patient personally appeared before me and signed above or acknowledged the signature above as his or her own. I declare under penalty of perjury that the patient appears to be of sound mind and under no duress, fraud, or undue influence.

My commission expires: _____ _____
Signature of Notary Public

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

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

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-11-224, and 68-11-1805.* ***Administrative History:*** *Original rule filed February 16, 2007; effective May 2, 2007. Repeal and new rule filed August 28, 2012; effective November 26, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendments filed February 8, 2017; effective May 9, 2017. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**From:** Nathaniel Flinchbaugh
**To:** Scott Faragher
**Subject:** FW: Questions for list of Quality programs
**Date:** Thursday, April 17, 2025 8:25:23 AM
**Attachments:** image002.png

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FYI

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**From:** Hannah Dudney <Hannah.Dudney@tn.gov>
**Sent:** Wednesday, April 16, 2025 4:32 PM
**To:** Holly Vickers <Holly.Vickers@tn.gov>
**Cc:** Thomas P. Pitt <Thomas.P.Pitt@tn.gov>; Phillip M. Earhart <Phillip.M.Earhart@tn.gov>; Nathaniel Flinchbaugh <Nathaniel.R.Flinchbaugh@tn.gov>
**Subject:** RE: Questions for list of Quality programs

Hi,
The Perinatal Advisory Committee (PAC) does not currently maintain a list of quality initiative programs. However, this is something that the NICU TAG and PAC would support if included in the NICU licensure process. The PAC has a proposed process for maintain a list of quality initiatives that would meet the licensure requirement.

- The PAC will draft and vote on a list of approved programs.
- In order to assure contemporary pertinence of the list of approved quality initiative programs, the Perinatal Advisory Committee has limited its approval to a period no longer than five years from the date of approval by the Commissioner of the Department of Health. A revision of the list will be mandatory at that time, unless one becomes necessary at an earlier date. (This is the same approval and review process for our other guidelines, maintained by PAC.)
- To add or remove an entity from the list, a request is made in writing to the PAC. The request will be distributed to PAC members prior to the next meeting (the committee meets three times a year), and the members will vote on it at the next meeting.

The NICU TAG has recommended the following programs:

- Tennessee Initiative for Perinatal Quality Care (TIPQC)
- Solutions for Patient Safety (SPS)
- Children's Hospital's Neonatal Consortium (CHNC)
- Vermont Oxford Network (VON)

I can answer your questions about Tennessee Initiative for Perinatal Quality Care (TIPQC) since the Department of Health works closely with this program. I don't have the answers to the others since I have not worked directly with these programs. I would recommend asking members of the NICU TAG for additional information. Dr Lattimore did provide me with the information that she thinks the VON

cost is 1800-2000 yearly, with additional cost to participate in the database. I don't have information about the cost of SPS or CHNC. With TIPQC, participation in the initiatives is free of charge. It is offered every year, and NICUs can join at any time. The average duration of a project is about a year (range 1-2 years). TIPQC provides certificates to participating facilities on an annual basis.

Best regards,
HD

**Hannah Dudney, MD, FACOG** | Associate Medical Director, Women's Health
Tennessee Department of Health
Division of Family Health and Wellness
Andrew Johnson Tower
710 James Robertson Parkway, Nashville, TN 37243
Hannah.Dudney@tn.gov
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**From:** Holly Vickers <Holly.Vickers@tn.gov>
**Sent:** Friday, April 11, 2025 12:41 PM
**To:** Hannah Dudney <Hannah.Dudney@tn.gov>
**Cc:** Thomas P. Pitt <Thomas.P.Pitt@tn.gov>; Phillip M. Earhart <Phillip.M.Earhart@tn.gov>; Nathaniel Flinchbaugh <Nathaniel.R.Flinchbaugh@tn.gov>
**Subject:** Questions for list of Quality programs

Good afternoon Dr. Dudney,

I just wanted to forward some questions that were posed that maybe you could help to answer .

The TAG references the "list of approved quality programs" that is maintained by PAC and qualified through TIPQC.

1. How many are free?
2. What is the average cost for those with charge?
3. How often are they offered?
4. What is the duration?
5. How is an entity added to the approved list?

**Holly Vickers** | Health Planner Quality Officer
Health Facilities Commission
Andrew Jackson State Office Building, 9th Floor
502 Deaderick Street, Nashville, TN 37243
P: 615-741-7999
holly.vickers@tn.gov


tn.gov/hfc

***Mission Statement:*** *To promote access to quality, cost-effective healthcare in Tennessee*

**From:** Jim Christoffersen
**To:** Nathaniel Flinchbaugh; Scott Faragher
**Subject:** Re: NICU Draft rules feedback
**Date:** Thursday, April 17, 2025 10:00:57 AM
**Attachments:** image002.png

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Hmmm ... what are your thoughts on the specific proposed amendments?

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**From:** Nathaniel Flinchbaugh <Nathaniel.R.Flinchbaugh@tn.gov>
**Sent:** Thursday, April 17, 2025 8:25 AM
**To:** Scott Faragher <Scott.Faragher@tn.gov>; Jim Christoffersen <Jim.Christoffersen@tn.gov>
**Subject:** FW: NICU Draft rules feedback

FYI

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**From:** Hannah Dudney <Hannah.Dudney@tn.gov>
**Sent:** Wednesday, April 16, 2025 5:00 PM
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**Cc:** Elizabeth Harvey <Elizabeth.Harvey@tn.gov>
**Subject:** NICU Draft rules feedback

Hi HFC team and NICU TAG,

I have provided the attached feedback based on the draft rules. You will also see comments from Margaret Major, TDH Director of Perinatal, Infant, and Pediatric Care. I am happy to meet with you if needed to discuss the feedback. The attached document is a PDF best viewed in Adobe Acrobat. Click the comments tab on the right to view comments. If you cannot view the comments, please let me know.

I did not include feedback in the document about the quality portion that we discussed at last week's meeting. But, would recommend something along the lines of "All NICUs must demonstrate a commitment to evidence-based practices through annual participation in a quality initiative each time they are verified or reverified. NICUs will submit proof of participation by providing

documentation of participation, such as a certification of participation from the quality initiative organization. The Perinatal Advisory Committee will maintain a list of quality initiative programs that would meet the licensure requirement."

Best regards,
HD

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**From:** Holly Vickers <Holly.Vickers@tn.gov>
**Sent:** Thursday, April 10, 2025 7:21 AM
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**Subject:** Draft rules link

Good morning all,

I wanted to share that the draft rules have been posted if you would like to look over them at your convenience. You can find a direct link to them here: 4E4-Rules_0720-14_Draft_Hospital_Rules.pdf

New additions have been added in blue/underlined; the red/strikethroughs no-longer apply.

Please let me know if you have any feedback or questions. Have a great day!

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***Mission Statement:*** *To promote access to quality, cost-effective healthcare in Tennessee*

**RULES**
**OF**
**THE TENNESSEE HEALTH FACILITIES COMMISSION**

**CHAPTER 0720-14**
**STANDARDS FOR HOSPITALS**

**TABLE OF CONTENTS**



## 0720-14-.01 DEFINITIONS.

(1) AAP. Means American Academy of Pediatrics.

~~(1) Abuse. The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.~~

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

(a) How the deficiency will be corrected.

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

(c) The date the deficiency will be corrected.

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

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

(5) Acute Burn Care. The medical treatment of burn injuries during the initial weeks after the injury.

~~(3)~~(6) Adult. An individual who has capacity and is at least 18 years of age.

~~(4)~~(7) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

~~(5)~~(8) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

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

(9) Burn. Medically defined as a painful injury to the skin or other tissue caused by heat, electricity, radiation, chemicals, or friction.

(10) Burn Unit. A burn unit must belong to a general hospital that is Joint Commission accredited, or American Burn Association (ABA) verified.

(11) Burn Unit Director. An appropriately licensed surgeon (MD or DO) with the following:

(a) Board certification by the American Board of Surgery or American Board of Plastic Surgery,

(b) Within the preceding five years, one of the following:

1. A one-year fellowship in burn treatment, or

2. Two years of experience treating acute burn injuries.

(c) Advanced Burn Life Support (ABLS) certification.

(12) Burn Nurse Leader. An appropriate licensed Registered Nurse with the following:

(a) A minimum of a baccalaureate degree in nursing,

(b) Two years of acute burn treatment experience, or a training program designed by the Burn Unit Director to ensure competency,

(c) Advanced Burn Life Support (ABLS) certification.

~~(7)~~(13) 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

~~(8)~~(14) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

~~(9)~~(15) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

~~(10)~~(16) Certified Nurse Practitioner. A person who is licensed as a registered nurse and has further been issued a certificate of fitness to prescribe and/or issue legend drugs by the Tennessee Board of Nursing.

~~(11)~~(17) 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)~~(18) Certified Respiratory Therapist. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

~~(13)~~(19) Certified Respiratory Therapy Technician. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

~~(14)~~(20) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

~~(15)~~(21) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians and mid-level practitioners.

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

(23) Commission. The Tennessee Health Facilities Commission.

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

~~(17)~~(24) Competent. A patient who has capacity.

~~(18) Critical Access Hospital. A hospital located in a rural area, certified by the Department as being a necessary provider of health care services to residents of the area, which makes available twenty-four (24) hour emergency care; is a designated provider in a rural health network; provides not more than twenty-five (25) acute care inpatient beds for providing inpatient care not to exceed an annual average of ninety-six (96) hours, and has a quality assessment and performance improvement program and procedures for utilization review. If swing-bed approval has been granted, all twenty-five (25) beds can be used interchangeably for acute or Skilled Nursing Facility (SNF/swing-bed) level of care services.~~

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

~~(19)~~(26) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

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

~~(21)~~(27) 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)~~(28) Designation. An official finding and recognition by the Commission that an acute care hospital meets Tennessee State Rural Health Care Plan requirements to be a Critical Access Hospital or Rural Emergency Hospital.

~~(23)~~(29) Dietitian. As used in the chapter, the term "dietitian" means:

(a) A person who is currently licensed by the Tennessee Board of Dietitian/Nutritionist Examiners as a dietitian/nutritionist; or

(b) An employee of a Tennessee hospital who is exempt from Tennessee licensure pursuant to T.C.A. § 63-25-104(b)(6) but holds the credential of Registered Dietitian (RD) or Registered Dietitian Nutritionist (RDN) from the Commission on Dietetic Registration.

~~(24)~~(30) 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.

(31) E. Means essential requirement.

~~(25)~~(32) 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.

~~(26)~~(33) 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.

~~(27)~~(34) 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.

(35) Executive Director. The Executive Director of the Tennessee Health Facilities Commission.

~~(28)~~(36) 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.

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

(38) Guidelines for Perinatal Care. An educational resource to aid clinicians in providing obstetric and gynecological care developed through the collaborative efforts of the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG).

~~(29)~~(39) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

~~(30)~~(40) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

~~(31)~~(41) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

~~(32)~~(42) 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 0720-14-.13 or T.C.A. § 33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

~~(33)~~(43) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

~~(34)~~(44) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

~~(35)~~(45) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more non-related persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment. All hospitals shall provide basic hospital functions and may provide optional services as delineated in these rules. A hospital shall be designated according to its classification and shall confine its services to those classifications described below.

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

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

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

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

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

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

6. An emergency department in accordance with Rule 0720-14-.07(5) of these standards and regulations.

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

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

(c) Chronic Disease Hospital. To be licensed as a chronic disease hospital, the institution shall be devoted exclusively to the diagnosis, treatment or care of persons needing medical, surgical or rehabilitative care for chronic or long-term illness, injury, or infirmity. The diagnosis, treatment or care shall be administered by or performed under the direction of persons currently licensed to practice the healing arts in the State of Tennessee. A chronic disease hospital shall meet the requirements for a general hospital except that obstetrical facilities are not required and, if the hospital provides no surgical services, an emergency department is not required.

(d) Orthopedic Hospital. To be licensed as an orthopedic hospital, the institution shall be devoted primarily to the diagnosis and treatment of orthopedic conditions. An orthopedic

hospital shall meet the requirements for a general hospital except that obstetrical services are not required and, if the hospital provides no surgical services, an emergency department is not required.

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

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

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

~~(36)~~(46) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such persons, and maternity care involving labor and delivery for any period of time.

~~(37)~~(47) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

~~(38)~~(48) Individual Instruction. An individual's direction concerning a health care decision for the individual.

~~(39)~~(49) 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.

~~(40)~~(50) Involuntary Transfer. The movement of a patient between hospitals, without the consent of the patient, the patient's legal guardian, next of kin or representative.

~~(41)~~(51) Justified Emergency. Includes, but is not limited to, the following events/occurrences:

(a) An influx of mass casualties;

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

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

~~(42)~~(52) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

~~(43)~~(53) Licensed Health Care Professional. Any health care professional currently licensed by the State of Tennessee to practice within the scope of a regulated profession, such as a nurse practitioner, dietitian, dentist, occupational therapist, pharmacist, physical therapist,

physician, physician assistant, podiatrist, psychologist, clinical social worker, speech language pathologist, and emergency service personnel.

~~(44)~~(54) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

~~(45)~~(55) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

~~(46)~~(56) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(57) 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.

~~(47)~~(58) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part, which includes labor when delivery is imminent, when there is inadequate time to effect safe transfer to another hospital prior to delivery, or when a transfer may pose a threat to the health and safety of the patient or the unborn child.

~~(48)~~(59) 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.

~~(49)~~(60) Medical Staff. An organized body composed of individuals appointed by the hospital governing board that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

~~(50)~~(61) 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.

~~(51)~~(62) Member of the Professional Medical Community. A professional employed by the hospital and on the premises at the time of a voluntary delivery.

~~(52)~~(63) Mid-Level Practitioner. Either a certified nurse practitioner or a physician assistant.

~~(53)~~(64) 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.

~~(54)~~(65) 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. N.F.P.A. The National Fire Protection Association.

(66) Neonatal Care Units.

(a) Level II. Level II nurseries provide specialty neonatal services. They provide care for stable or moderately ill infants born at >32 weeks gestation and weighing >1500 grams who have problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis. These units also resuscitate and stabilize preterm and/or ill infants before transfer to a facility at which newborn intensive care is provided. Level II nurseries provide mechanical ventilation for brief (<24 hrs) duration and continuous positive airway pressure, until the infant's condition improves, or the infant can be transferred to a higher-level facility (American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012). In addition, Level II units provide care for infants who are convalescing after intensive care.

(b) Level III. Level III nurseries provide care for infants who are born at <32 weeks of gestation or weigh <1500 grams at birth or have complex medical or surgical conditions, regardless of gestational age. Level III units have continuously available personnel and equipment to provide life support for as long as needed. They can provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily accessible on site or by prearranged consultative agreements (American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012).

(c) Level IV. Level IV units include the capabilities of Level III units with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants. Pediatric medical and pediatric surgical specialty consultants must be continuously available 24 hours a day, 7 days a week. Level IV facilities also must have the capability for surgical repair of complex conditions (e.g., congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation) (American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012).

(67) Neonatal Intensive Care Unit (NICU). Shall have the same definition as provided in T.C.A. § 68-59-102(6).

(68) Neonatal Intensive Care Unit (NICU) Director. Please refer to 0720-14-.07(17)(b)(i).

(69) Neonatal Intensive Care Unit (NICU) Nurse Manager. Please refer to 0720-14-.07(17)(b)(ii).

(70) Neonatal Resuscitation Program (NRP). Is an evidence-based approach for the immediate resuscitation care of a newborn at birth, which was developed by the American Academy of Pediatrics (AAP) and the American Heart Association (AHA). NRP covers neonatal resuscitation equipment, administering neonatal CPR, and other lifesaving measures.

~~(55)~~(71) N.F.P.A. The National Fire Protection Association.

~~(56)~~(72) Nuclear Medicine Technologist. A person currently registered as such by the National Association for Nuclear Medicine Technology.

~~(57)~~(73) 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.

~~(58)~~(74) Occupational Therapist. A person currently certified as such by the Tennessee Board

of Occupational and Physical Therapy Examiners.

~~(59)~~(75) Occupational Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

~~(60)~~(76) Optometrist. A person currently licensed as such by the Tennessee Board of Optometry.

~~(61)~~(77) 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.

(78) Perinatal Advisory Committee (PAC). The Perinatal Advisory Committee was established by statute and exists as a consultative body to advise the Tennessee Department of Health in administration and implementation of the perinatal regionalization system across Tennessee. The Committee is composed of individuals with expertise and a vested interested in the health and wellbeing of pregnant women and newborns, including the State's Title V / MCH Block Grant Director, Co-directors of each of the five perinatal centers, as well as representation from local hospitals, medical specialists in obstetrics and newborn conditions/private practice, family physicians, obstetrical and neonatal intensive care nurses, a medical school, and the general public. (TCA §§ 68-1-803-804)

~~(62)~~(79) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

~~(63)~~(80) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

~~(64)~~(81) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

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

~~(65)~~(83) Physical Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

~~(66)~~(84) Physical Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

~~(67)~~(85) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

~~(68)~~(86) Physician Assistant. A person who has graduated from a physician assistant educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a physician assistant under Title 63, Chapter 19.

~~(69)~~(87) Physician Orders for Scope of Treatment or POST. Written orders that:

~~(a) Are on a form approved by the Board for Licensing Health Care Facilities;~~

(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) 1. Specify whether, in the event the patient suffers cardiac or respiratory arrest,

cardiopulmonary resuscitation should or should not be attempted;

2. Specify other medical interventions that are to be provided or withheld; or

3. Specify both 1. and 2.

~~(70)~~(88) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

~~(71)~~(89) 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.

(90) Program Objectives Report (POR). Defines the goals and projected results of a program.

~~(72)~~(91) Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

~~(73)~~(92) 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.

~~(74)~~(93) Radiological Technologist. A person currently registered as such by the American Society of Radiological Technologists.

~~(75)~~(94) 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.

(95) Regional Perinatal Center. Acts as a referral hub for hospitals that are unable to handle more complex maternal and neonatal cases to meet the needs of high-risk infants and women.

~~(76)~~(96) Registered Health Information Administrator (RHIA). A person currently registered as such by the American Health Information Management Association.

~~(77)~~(97) Registered Health Information Technician (RHIT). A person currently accredited as such by the American Health Information Management Association.

~~(78)~~(98) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

~~(79)~~(99) Rural Area. A county classified by the federal Office of Management and Budget (OMB) as rural, all counties, excluding Davidson, Hamilton, Knox, and Shelby, currently defined as rural in Chapter 1200-20-11 of the Tennessee Comprehensive Rules and Regulations, or an area outside of a county or part of a county previously classified as rural by the OMB and reclassified by the OMB as a metropolitan statistical area as of June 6, 2003.

~~(80)~~(100) Rural Emergency Hospital. A Rural Emergency Hospital ("REH") is a facility that:

(a) Meets the eligibility requirements for a licensed hospital in Tennessee pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(37), and the following additional requirements:

1. Is enrolled for reimbursement as a rural emergency hospital by the federal Centers for Medicare and Medicaid Services pursuant to 42 U.S.C. §§ 1395x(kkk) et. seq. and 42 U.S.C. § 1395cc(j), or any successor statute;

2. Provides rural emergency hospital services;

3. Provides an emergency department which maintains:

   (i) Availability twenty-four (24) hours a day seven (7) days per week.

   (ii) A physician, physician assistant, or nurse practitioner, who performs such services as such individual is legally authorized to perform in accordance with state law and who meets training, education, and experience requirements required by state law.

   (iii) Such clinician must be on call at all times and available on-site within thirty (30) minutes to sixty (60) minutes depending on the facility's location.

   (iv) Staffed twenty-four (24) hours per day and (7) seven days per week by individuals competent in the skills needed to address emergency medical care and must be able to receive patients and activate appropriate medical resources to meet the care needed by patients.

4. Has a transfer agreement in effect with a level I or level II trauma center; and

5. Meets such other licensure, staff training and education requirements as the Health Facilities Commission finds necessary in the interest of the health and safety of individuals who are provided rural emergency hospital services.

6. A Rural Emergency Hospital does not have inpatient beds or provide any acute inpatient services, other than those which are rendered by a licensed skilled nursing facility to furnish post-hospital extended care services, which is a distinct part unit of the Rural Emergency Hospital.

7. Nothing in this definition expands on the scope of a licensed healthcare professional's ability to practice under their respective regulated profession.

~~(81)~~(101) Rural Emergency Hospital Services. The term "rural emergency hospital services" means the following services, provided by a Rural Emergency Hospital, that do not exceed an annual per-patient average of twenty-four (24) hours in such Rural Emergency Hospital:

(a) Emergency department services, and observation care; and

(b) At the election of the Rural Emergency Hospital, for services provided on an outpatient basis, other medical and health services as specified in regulations adopted by the United States Secretary of Health and Human Services and authorized by the applicable rules or statutes of the Health Facilities Commission.

(102) S.T.A.B.L.E. (Sugar, Temperature, Airway, Blood pressure, Lab work, Emotional support). Is a neonatal educational program that focuses on the post-resuscitation and stabilization of newborns.

~~(82)~~(103) Satellite Hospital. A freestanding hospital licensed with a parent hospital that is on separate premises and operated under the same management.

~~(83)~~(104) Shall or Must. Compliance is mandatory.

~~(84)~~(105) Social Worker. A person who has at least a bachelor's degree in Social Work or related field, and preferably, two (2) years medical social work or other community based work experience.

~~(85)~~(106) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified

medical personnel when a physician is not readily available.

~~(86)~~(107) 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.

~~(87)~~(108) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board.

~~(88)~~(109) 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.

~~(89)~~(110) Surgical Technologist. A person who works under supervision to facilitate the safe and effective conduct of invasive surgical procedures. This individual is usually employed by a hospital, medical office, or surgical center and supervised during the surgical procedure according to institutional policy and procedure to assist in providing a safe operating room environment that maximizes patient safety by performing certain tasks including, but not limited to:

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

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

(c) Passing instruments, equipment or supplies to a surgeon, sponging or suctioning an operative site, preparing and cutting suture material, holding retractors, transferring but not administering fluids or drugs, assisting in counting sponges, needles, supplies, and instruments, and performing other similar tasks as directed during a surgical procedure.

~~(90)~~(111) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(112) T-Piece Resuscitator. Is devised of a T shaped circuit which is utilized in neonatal resuscitation to deliver positive pressure ventilation (PPV). To determine a consistent, Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP) the operator can adjust the dials on the device.

(113) Tennessee Initiative for Perinatal Quality Care (TIPQC). Implements evidence-based practices focusing on enhancing health outcomes for mothers and newborns throughout Tennessee. Founded in 2008 through a grant from the Governor's Office to engage hospitals, practitioners, payers, families, and communities to promote meaningful change, advance health equity, and improve the quality of care through pregnancy, delivery and beyond for all Tennessee families.

(114) Tennessee Hospital Association (THA). Established in 1938, THA is a not-for-profit membership organization serving and promoting the interests of hospitals, health systems, and other healthcare organizations in the state.

(115) Tennessee Perinatal Care System Educational Objectives for Nurses. Developed by a group of experienced obstetric and neonatal nurse educators, list the knowledge and skills necessary to provide quality nursing care to mothers and newborns.

(116) Tennessee Perinatal Care System Educational Objectives in Medicine for Perinatal Social Workers. Means objectives ensuring social workers are equipped to improve maternal and infant health outcomes by enhancing the knowledge and skills essential in perinatal care.

(117) Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing, and Facilities 2020 Edition. Guidelines are written in response to the recommendation

of the Perinatal Advisory Committee, describe components of various care levels, and are developed to accomplish improvement in perinatal outcomes in Tennessee by providing quality care to every mother and newborn.

(118) Tennessee Perinatal Care System Guidelines for Transportation. Guidelines are written in response to the recommendation of the Perinatal Advisory Committee and are developed to accomplish improvement in the overall quality of maternal-neonatal transportation in the state. The guidelines provide specific guidelines regarding procedures, staffing patterns, and equipment for the transport of high-risk mothers and infants.

(119) Total Parenteral Nutrition (TPN). Is delivered through a PICC (Peripherally Inserted Central Catheter – a catheter inserted into the inner aspect of the bend of the arm or the middle of the upper arm) line, subclavian or internal jugular veins. TPN is typically administered when a patient requires extensive nutritional support that cannot be achieved by any other means.

~~(91)~~(120) Transfer. The movement of a patient between hospitals at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice. The term does not apply to the commitment and movement of mentally ill and mentally retarded persons and does not apply to the discharge or release of a patient no longer in medical need of hospital care or to a hospital's refusal, after an appropriate medical screening, to render any medical care on the grounds that the person does not have a medical need for hospital care.

~~(92)~~(121) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(93)~~(122) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such person may be deemed to be the "treating physician."

~~(94)~~(123) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a hospital with any hospital employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1602; 68-11-1802, 68-57-101, 68-57-102, and 68-57-105; 42 U.S.C. § 1395x(kkk); and 42 U.S.C. § 1395cc(j).* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed November 30, 1984; effective December 30, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 26, 1996; effective July 8, 1996. Amendment filed November 30, 1999; effective February 6, 2000. Repeal, except for Paragraphs (1), (5), (8), (10), (11), (13), (16), (29), and (37) as promulgated February 6, 2000, and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed August 27, 2004; effective November 10, 2004. Amendments filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendments filed March 18, 2010; effective June 16, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed April 25, 2016; effective July 24, 2016. Amendments filed July 10, 2018; effective October 8, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022. Emergency rules filed December 27, 2022; effective through June 25, 2023. Emergency rules expired effective June 26, 2023, and the rules reverted to their previous statuses. Amendments filed August 11, 2023; effective November 9, 2023.*

**0720-14-.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 hospital 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 and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the hospital.~~

(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 hospital or any of the following optional services; Burn Unit, MRI Unit, NICU, or PET Unit 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 and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the hospital.

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

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

(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 based on the number of hospital beds. 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 hospital until a license has been issued. Applicants shall not hold themselves out to the public as being a hospital 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 T.C.A. § 68-11-206(1), or as later amended, and of all information required by the Commissioner.~~

(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. Patients shall not be admitted to the hospital until a license has been issued. Applicants shall not hold themselves out to the public as being a hospital 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 T.C.A. § 68-11-206(1), or as later amended, and of all information required by the Commission.

(d) The applicant must prove the ability to meet the financial needs of the facility.

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

~~(f) The applicant shall allow the hospital to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.~~

(f) The applicant shall allow the hospital 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) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.~~

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Commission a minimum of thirty (30) 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 a hospital 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 the hospital's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the hospital is owned and operated.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled;

7. The consolidation of a corporate facility owner with one or more corporations; or,

8. Transfers between levels of government.

9. 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; or,

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.

7. Management agreements where the owner continues to retain ultimate authority for the operation of the facility.

~~(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.~~

~~(f)~~(e) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

~~(4) Each hospital, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the department a fee based on the number of hospital beds, as follows:~~

(4) Each hospital, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the Commission a fee based on the number of hospital beds, as follows:

| | | |
|---|---|---|
| (a) | Less than 25 beds | $ 1,040.00 |
| (b) | 25 to 49 beds, inclusive | $ 1,300.00 |
| (c) | 50 to 74 beds, inclusive | $ 1,560.00 |
| (d) | 75 to 99 beds, inclusive | $ 1,820.00 |
| (e) | 100 to 124 beds, inclusive | $ 2,080.00 |
| (f) | 125 to 149 beds, inclusive | $ 2,340.00 |
| (g) | 150 to 174 beds, inclusive | $ 2,600.00 |
| (h) | 175 to 199 beds, inclusive | $ 2,860.00 |

For hospitals of two hundred (200) beds or more the fee shall be two thousand eight hundred and sixty dollars ($2,860.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(5) Each hospital choosing to operate one of the following optional services shall pay annually to the Commission a per unit non-refundable fee, as follows:

| | | |
|---|---|---|
| (a) | Burn Unit | $ 1,040.00 |
| (b) | NICU | $ 1,040.00 |
| (c) | MRI Unit | $ 500.00 |
| (d) | PET Unit | $ 500.00 |

~~(5)~~(6) Renewal.

~~(a) In order to renew a license, each hospital shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.~~

(a) In order to renew a license, each hospital 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 corrective action 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) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

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

(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 0720-14-.02(4); and

~~3. Any other information required by the Health Services and Development Agency.~~

3. Any other information required by the Commission.

~~(d) Upon reapplication, the licensee shall submit to an inspection of the hospital by Department of Health surveyors.~~

(d) Upon reapplication, the licensee shall submit to an inspection of the hospital by Commission surveyors.

***Authority:*** *T.C.A. §§ 4-5-201, 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-206(a)(5), 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, § 1.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed January 16, 1992; effective March 2, 1992. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed March 21, 2018; to have been effective June 19, 2018. However, on May 24, 2018, the Government Operations Committee filed a 5-day stay; new effective date June 24, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.03 DISCIPLINARY PROCEDURES.**

~~(1) The board may suspend or revoke a license for:~~

(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;

(c) Permitting, aiding or abetting the commission of any illegal act in the hospital;

~~(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the hospital; and~~

(d) Conduct or practice found by the Commission to be detrimental to the health, safety, or welfare of the patients of the hospital; and

(e) Failure to renew license.

~~(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:~~

(2) The Commission may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

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

~~(d) Any prior violations by the facility of statutes, regulations or orders of the board.~~

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

(3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke a hospital's license.

~~(4) When a hospital 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 deficiencies, the hospital must return a plan of correction indicating the following:~~

(4) When a hospital is found by the Commission to have committed a violation of this chapter, the Commission will issue to the facility a statement of deficiencies. Within ten (10) calendar days of the receipt of the deficiencies, the hospital 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.

~~(5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the hospital's license to possible disciplinary action.~~

(5) 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 the hospital's license to possible disciplinary action.

~~(6) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §§ 4-5-101, et seq.~~

(6) 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 Commission's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §§ 4-5-101, et seq.

~~(7) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to Rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.~~

(7) 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.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-208, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed December 30, 1986; effective February 13, 1987. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed March 1, 2007; effective May 15, 2007. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.04 ADMINISTRATION.**

(1) The hospital must have an effective governing body legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this chapter.

(2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital. 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 hospital with administrative direction at all times.

(3) When licensure is applicable for a particular job, the number and renewal number of the current license or a copy of the internet verification of such license must be maintained in personnel. 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.

(4) 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 hospital which violates a required policy also violates the rule and regulation establishing the requirement.

(5) Policies and procedures shall be consistent with professionally recognized standards of

practice.

~~(6) No hospital 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. A hospital 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.~~

(6) No hospital 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 hospital 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.

(7) The hospital shall ensure a framework for addressing issues related to care at the end of life.

(8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(9) Critical Access Hospital.

(a) The facility shall enter into agreements with one or more hospitals participating in the Medicare/Medicaid programs to provide services which the Critical Access Hospital is unable to provide.

(b) When there are no inpatients, the facility is not required to be staffed by licensed medical professionals, but must maintain a receptionist or other staff person on duty to provide emergency communication access. The hospital shall provide an effective system to ensure that a physician or a mid-level practitioner with training and experience in emergency care is on call and immediately available by telephone or radio and available on site within thirty (30) minutes, twenty-four (24) hours a day.

(10) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

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

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

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

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

(11) "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.

(12) Hospice services may be provided in an area designated by a hospital for exclusive use by a home care organization certified as a hospice provider to provide care at the hospice inpatient

or respite level of care in accordance with the hospice's Medicare certification. Admission to the hospital is not required in order for a patient to receive such hospice services, regardless of the patient's length of stay. The designation by a hospital of a portion of its facility for exclusive use by a home care organization to provide hospice services to its patients shall not:

(a) Alter the license to bed complement of such hospital, or

(b) Result in the establishment of a residential hospice.

(13) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

(14) Informed Consent.

(a) Any hospital in which abortions, other than abortions necessary to prevent the death of the pregnant female, are performed shall conspicuously post a sign in a location defined below so as to be clearly visible to patients, which reads:

Notice: It is against the law for anyone, regardless of the person's relationship to you, to coerce you into having or to force you to have an abortion. By law, we cannot perform an abortion on you unless we have your freely given and voluntary consent. It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.

(b) The sign shall be printed in languages appropriate for the majority of clients of the hospital with lettering that is legible and that is Arial font, at least 40-point bold-faced type.

(c) A hospital in which abortions are performed that is not a private physician's office or ambulatory surgical treatment center shall post the required sign in the admissions or registration department used by patients on whom abortions are performed.

~~(d) A hospital shall be assessed a civil penalty by the Board for Licensing Health Care Facilities of two thousand five hundred dollars ($2,500.00) for each day of violation in which:~~

(d) A hospital shall be assessed a civil penalty by the Commission of two thousand five hundred dollars ($2,500.00) for each day of violation in which:

1. The sign required above was not posted during business hours when patients or prospective patients are present; and

2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the hospital.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 39-15-202, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268, and 71-6-121.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendments filed February 22, 2010; effective May 23, 2010. Amendment filed December 16, 2013; effective March 16, 2014. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.**

(1) Every person admitted for care or treatment as an inpatient to any hospital covered by these rules shall be under the supervision of a physician who holds an unlimited license to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to a hospital by licensed health care professional, licensed to practice in Tennessee with the concurrence of a credentialed MD/DO also licensed to practice in Tennessee if admission by a category of licensed health care professionals is provided for in the medical staff bylaws. The licensed health care professional may also provide on call services to patients in the hospital if on call services for a category of licensed health care professionals is so provided for in the medical staff bylaws. The name of the attending licensed health care professional shall be recorded in the patient medical record as well as the name of the credentialed MD/DO. If a hospital allows these licensed health care professionals to admit and care for patients, as allowed by state law, the governing body and medical staff shall establish policies and bylaws, if necessary, to ensure that the requirements of 42 CFR part 482 are met.

(3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.

(4) A diagnosis must be entered in the admission records of the hospital for every person admitted for care or treatment.

(5) Except in emergency situations, no medication or treatment shall be given or administered to any inpatient in a hospital except on the order of a physician, dentist, or podiatrist lawfully authorized to give such an order. This requirement shall not apply to physical therapy, occupational therapy or speech language pathology services being provided in an outpatient setting when the services are being provided consistent with the scope of practice of physical therapists, occupational therapists and speech language pathologists as set forth in their respective practice acts found in Tennessee Code Annotated, Title 63, Chapters 13 and 17.

(6) 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.

(7) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established hospital protocol or rules.

(8) The hospital must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The hospital's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission of any patient who is likely to suffer adverse health consequences;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician;

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-hospitalization environment;

(e) Identify the patient's continuing physical, emotional, housekeeping, transportation, social and other needs and must make arrangements to meet those needs;

(f) Be completed on a timely basis to allow for arrangement of post-hospital care and to avoid unnecessary delays in discharge;

(g) Involve the patient, the patient's family or individual acting on the patient's behalf, the attending physician, nursing and social work professionals and other appropriate staff, and must be documented in the patient's medical record; and

(h) Be conducted on an ongoing basis throughout the continuum of hospital care. Coordination of services may involve promoting communication to facilitate family support, social work, nursing care, consultation, referral or other follow-up.

(9) A discharge plan is required on every patient, even if the discharge is to home.

(10) The hospital must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(11) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-hospital care.

(12) The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

(13) The governing body of each hospital must adopt transfer and acceptance policies and procedures in accordance with these rules and the provisions of T.C.A. §§ 68-11-701 through 68-11-705. These policies must include a review of all such involuntary transfers, with special emphasis on those originating in the emergency room.

(14) Transfer agreements with other health care facilities are subject to these statutory and regulatory provisions.

(15) When a hospital proceeding in compliance with these rules seeks to appropriately transfer a patient to another hospital, the proposed receiving hospital may not decline the transfer for reasons related to the patient's ability to pay or source of payment, rather than the patient's need for medical services. The determination of the availability of space at the receiving hospital may not be based on the patient's ability to pay or source of payment.

(16) Anyone arriving at a hospital and/or the emergency department of a hospital requesting or requiring an examination or treatment for a medical condition must be provided an appropriate medical screening examination within the capability of the hospital's staff to determine whether or not a medical emergency exists.

(17) The hospital must provide further medical examination and treatment as may be required to stabilize the medical emergency within the hospital's available staff and facilities. Such treatment may include, but is not limited to, the following:

(a) Establishing and assuring an adequate airway and adequate ventilation;

(b) Initiating control of hemorrhage;

(c) Stabilizing and splinting the spine or fractures;

(d) Establishing and maintaining adequate access routes for fluid administration;

(e) Initiating adequate fluid and/or blood replacement; and

(f) Determining that the patient's vital signs (including blood pressure, pulse, respiration, and urinary output, if indicated) are sufficient to sustain adequate perfusion.

(18) A hospital is deemed to meet the requirements of this section with respect to an individual if:

(a) The hospital offers to provide the further medical examination and treatment necessary but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the examination or treatment; or

(b) The hospital offers to transfer the individual to another hospital in accordance with this section but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the transfer.

(19) If a patient at a hospital has not been or cannot be stabilized within the meaning of this section, the hospital may not transfer the patient unless:

(a) The patient, or legally responsible person acting on the patient's behalf, requests that a transfer be implemented after having been given complete and accurate information about matters pertaining to the transfer decision including:

1. The medical necessity of the movement;

2. The availability of appropriate medical services at both the transferring and receiving hospitals;

3. The availability of indigent care at the hospital initiating the transfer and the facility's legal obligations, if any, to provide medical services without regard to the patient's ability to pay; and,

4. Any obligation of the hospital through its participation in medical assistance programs of the federal, state or local government to accept the medical assistance program's reimbursement as payment in full for the needed medical care.

(b) A physician, or other appropriately qualified medical personnel when a physician is not available, makes a determination based upon the reasonable risk, expected benefits to the patient, and current available information that the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risk to the individual's medical condition resulting from a transfer; and

(c) The transfer is appropriate within the meaning of this section.

(20) An appropriate transfer includes:

(a) A physician at the receiving hospital agreeing to accept transfer of the patient and to provide appropriate medical treatment;

(b) The receiving hospital having space available and personnel qualified to treat the patient;

(c) The transferring hospital providing the receiving hospital with appropriate medical records, or copies thereof, of any examination and/or treatment initiated by the

transferring hospital; and

(d) The transfer being effected with qualified personnel, appropriate transportation equipment, and the use of necessary and medically appropriate life support measures as required.

~~(21) Transfers made pursuant to a regionalized plan for the delivery of health care services, approved by the department or other authorized governmental planning agency, are presumed to be appropriate.~~

(21) Transfers made pursuant to a regionalized plan for the delivery of health care services, approved by the Commission or other authorized governmental planning agency, are presumed to be appropriate.

(22) After an appropriate transfer has been effected, the receiving hospital may transfer the patient back to the original hospital, and the original hospital may accept the patient, if:

(a) The original receiving hospital has stabilized the medical emergency or provided treatment of the active labor and the patient no longer has a medical emergency; and

(b) The transfer is made in accordance with (21) of this section.

~~(23) When a hospital determines the need to exceed its licensed bed capacity upon an occurrence of a justified emergency, the following procedures must be followed:~~

(23) When a hospital determines the need to exceed its licensed bed capacity upon an occurrence of a justified emergency, one of the following procedures must be followed:

(a) Short term need to exceed licensed bed capacity for a justified emergency

~~1. The hospital's administrator must make written notification to the Department within forty-eight (48) hours of exceeding its licensed bed capacity.~~

1. The hospital's administrator must make written notification to the Commission within forty-eight (48) hours of exceeding its licensed bed capacity.

2. The notification must include a detailed description of the emergency including:

(i) Why the licensed bed capacity was exceeded, i.e., lack of hospital beds in vicinity, specialized resources only available at the facility, etc.;

(ii) The estimated length of time the licensed bed capacity is expected to be exceeded; and,

(iii) The number of admissions in excess of the facility's licensed bed capacity.

~~3. As soon as the hospital returns to its licensed bed capacity, the administrator must notify the department in writing of the effective date of its return to compliance.~~

3. As soon as the hospital returns to its licensed bed capacity, the administrator must notify the Commission in writing of the effective date of its return to compliance.

~~4. Staff will review all notifications of excess bed capacity with the Chairman of the Board. If, upon review of the notification, department staff concurs that a justified emergency existed, staff will notify the facility in writing. A report of the occurrence will be made to the board at the next regularly scheduled meeting as information purposes only.~~

4. Staff will review all notifications of excess bed capacity with the Chairman of the Commission. If, upon review of the notification, Commission staff concurs that a justified emergency existed, staff will notify the facility in writing. A report of the occurrence will be made to the Commission at the next regularly scheduled meeting as information purposes only.

~~5. However, if department staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled board meeting to justify the need for exceeding its licensed bed capacity.~~

5. However, if Commission staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled Commission meeting to justify the need for exceeding its licensed bed capacity.

(b) Request a waiver of bed capacity not to exceed three (3) months.

1. If a waiver is being requested, notification must be given at the next regularly scheduled Commission meeting and include all of the following:

(i) Provide the number of beds requested under the waiver;

(ii) Provide the reason for the increase in bed capacity to include a description of the illness causing the need;

(iii) Provide an attestation that the required staffing levels can be met;

(iv) Provide the average expected length of stay;

(v) Provide an attestation that staffing levels can be maintained if the expected length of stay is exceeded; and

(vi) Provide a description of the location and area of the overflow

2. Administrative staff will review the request and may:

(i) Administratively approve the waiver; or

(ii) Administratively approve the waiver with conditions to protect the health, safety, and the welfare of the patients; or

(iii) Deny the waiver and request appearance before the Commission at the next regularly scheduled commission meeting.

(24) Infant Abandonment.

(a) Any hospital shall receive possession of any newborn infant left on hospital premises with any hospital employee or member of the professional medical community, if the infant:

1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;

2. Is left in an unharmed condition; and

3. Is voluntarily left by a person who purported to be the child's mother and who did not express

an intention of returning for the infant.

(b) The hospital, any hospital employee and any member of the professional medical community at such hospital shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The hospital shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The hospital may provide the parent contact information regarding relevant social service agencies, shall provide the mother the name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinquishment of the infant. If practicable, the hospital shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.

(c) The hospital, any hospital employee and any member of the professional medical community at such hospital shall perform any act necessary to protect the physical health or safety of the child.

(d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the hospital shall contact the Department of Children's Services, but shall not do so before the mother leaves the hospital premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.

(e) Notwithstanding any provision of law to the contrary, any hospital, any hospital employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause of action based upon violation of such existing standard of care for medical treatment.

(25) Caregiver.

(a) The hospital shall give a patient admitted to the hospital the opportunity to designate a caregiver who will assist the patient with continuing care after discharge from the hospital.

1. Caregiver means any individual designated as a caregiver by a patient who provides after-care assistance to a patient in a private residence. The term includes, but is not limited to, a relative, spouse, partner, friend or neighbor who has a significant relationship with the patient.

2. The hospital shall document the designated caregiver in the patient record and include contact information; and

3. If the patient declines to designate a caregiver, the hospital shall document the patient's choice in the medical record.

(b) The hospital shall notify the designated caregiver as soon as practicable before the patient is discharged back to a private residence.

(c) If the hospital is unable to contact the designated caregiver when changes occur, the lack of contact shall not interfere with, delay or otherwise affect the medical care provided to the patient or the transfer or discharge of the patient. Nothing in this paragraph shall interfere with, delay or otherwise affect the medical care provided to the patient or the transfer or discharge of the patient.

(d) The hospital shall make reasonable efforts to contact the designated caregiver and document those efforts in the patient record, to include dates and times attempted.

(e) The patient may give written consent to allow the hospital to release medical information to the designated caregiver, pursuant to the hospital's established procedures for the release of personal health information.

(f) Prior to the patient being discharged, the hospital shall provide discharge instructions for continuing care needs to the patient and designated caregiver, which shall include:

1. The name and contact information of the designated caregiver and relation to the patient;

2. A description of continuing care tasks that the patient requires, communicated in a culturally competent manner; and

3. Contact information for any health care, community resources, and long-term services and supports necessary to successfully carry out the patient's discharge instructions.

(g) Prior to the patient being discharged, the hospital shall provide the designated caregiver with an opportunity for instruction in continuing care tasks outlined in the discharge instructions, which shall include:

1. Demonstration of the continuing care tasks by hospital personnel; and

2. Opportunity for the patient and designated caregiver to ask questions and receive answers regarding the continuing care tasks; and

3. Education and counseling about medications, including dosing and proper use of delivery devices.

(h) The hospital shall document the instruction given to the patient and designated caregiver in the patient record, to include the date, time and contents of the instructions.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, and 68-11-255.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002. Amendments filed July 10, 2018; effective October 8, 2018. Amendments filed January 7, 2019; to have become effective April 7, 2019. However, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 6, 2019. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.06 BASIC HOSPITAL FUNCTIONS.**

(1) Performance Improvement.

(a) The hospital must ensure that there is an effective, hospital-wide performance improvement program to evaluate and continually improve patient care and performance of the organization.

(b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:

1. All organized services including services furnished by a contractor, are evaluated (all departments including engineering, housekeeping, and accounting need to show evidence of process improvement.);

2. Nosocomial infections and medication therapy are evaluated;

3. All medical and surgical services performed in the hospital are evaluated as to the appropriateness of diagnosis and treatment;

4. The competency of all staff is evaluated at least annually; and

5. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program, central venous catheter insertion process, and influenza vaccination program.

(c) The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically related needs of its patients which assures that:

1. Discharge planning is initiated in a timely manner; and

2. Patients, along with their necessary medical information, are transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.

(d) The hospital must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action.

(e) The hospital must demonstrate that the appropriate governing board or board committee is regularly apprised of process improvement activities, including identified deficiencies and the outcomes of remedial action.

(2) Medical Staff.

(a) The hospital shall have an organized medical staff operating under bylaws adopted by the medical staff and approved by the governing body, to facilitate the medical staff's responsibility in working toward improvement of the quality of patient care.

(b) The hospital and medical staff bylaws shall contain procedures, governing decisions or recommendations of appropriate authorities concerning the granting, revocation, suspension, and renewal of medical staff appointments, reappointments, and/or delineation of privileges. At a minimum, such procedures shall include the following elements: A procedure for appeal and hearing by the governing body or other designated committee if the applicant or medical staff feels the decision is unfair or wrong.

(c) The governing body shall be responsible for appointing medical staff and for delineating privileges. Criteria for appointment and delineation of privileges shall be clearly defined and included in the medical staff bylaws, and related to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the individual practitioner. Independent patient admission privileges shall only be granted to currently licensed doctors of medicine, osteopathy, podiatry, or dentistry.

(d) The medical staff must adopt and enforce bylaws to effectively carry out its responsibilities and the bylaws must:

1. Be approved by the governing body;

2. Include a statement of the duties and privileges of each category of medical staff;

3. Describe the organization of the medical staff;

4. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;

5. Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges; and

6. Include provisions for medical staff appointments granting active, associate, or courtesy medical staff membership, and/or provisions for the granting of clinical privileges. Such individuals must practice within the scope of their current Tennessee license, and the overall care of each patient must be under the supervision of a physician member of the medical staff.

(e) To be eligible for staff membership, an applicant must be a graduate of an approved program of medicine, dentistry, osteopathy, podiatry, optometry, psychology, or nurse-midwifery, currently licensed in Tennessee, competent in his or her respective field, and worthy in character and in matters of professional ethics.

(f) The medical staff shall be composed of currently licensed doctors of medicine, osteopathy, dentistry, and podiatry and may include optometrists, psychologists, and nurse-midwives. The medical staff must:

1. Periodically conduct appraisals of its members;

2. Examine the credentials of candidates for medical staff membership and make recommendations to the hospital on the appointment of the candidates; and

3. Participate actively in the hospital's process improvement plan implementation for the improvement of patient care delivery plans.

(g) The medical staff must be structured in a manner approved by the hospital or its governing body, well-organized, and accountable to the hospital for the quality of the medical care provided to the patient. Disciplinary action involving medical staff taken by the hospital shall be reported to the appropriate licensing board or professional society.

(h) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(i) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy, or a doctor of dental surgery or dental medicine.

(j) All physicians and non-employee medical personnel working in the hospital must adhere to the policies and procedures of the hospital. The Chief Executive officer or his or her designee shall provide for the adequate supervision and evaluation of the clinical activities of non-employee medical personnel which occur within the responsibility of the medical staff service.

(3) Infection Control.

(a) The hospital 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 chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff

develop guidelines and techniques for the prevention, surveillance, control and reporting of hospital infections. Duties of the committee shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the hospital;

3. Written procedures governing the use of aseptic techniques and procedures in all areas of the hospital, including adoption of a standardized central venous catheter insertion process which shall contain these key components:

   (i) Hand hygiene (as defined in 0720-14-.06(3)(g));

   (ii) Maximal barrier precautions to include the use of sterile gowns, gloves, mask and hat, and large drape on patient;

   (iii) Chlorhexidine skin antisepsis;

   (iv) Optimal site selection;

   (v) Daily review of line necessity; and

   (vi) Development and utilization of a procedure checklist;

4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A log of incidents related to infectious and communicable diseases;

6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;

7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies;

8. and Continuing education provided for all hospital personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.

(c) The administrative staff shall ensure the hospital prepares, and has readily available on site, an Infection Control Risk Assessment for any renovation or construction within existing hospitals. Components of the Infection Control Risk Assessment may include, but are not limited to, identification of the area to be renovated or constructed, patient risk groups that will potentially be affected, precautions to be implemented, utility services subject to outages, risk of water damage, containment measures, work hours for project, management of traffic flow, housekeeping, barriers, debris removal, plans for air sampling during or following project, anticipated noise or vibration generated during project.

(d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the hospital wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.

(e) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(f) A hospital 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 hospital 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 https://www.tn.gov/content/dam/tn/health/documents/SampleIndividualFluForm.pdf);

3. Education of all employees about the following:

(i) Flu vaccination,

(ii) Non-vaccine control measures, and

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

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

~~5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.~~

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

(g) All hospitals shall each year from October 1 through March 1offer the immunization for influenza and pneumococcal diseases to any inpatient who is sixty-five (65) years of age or older prior to discharging. This condition is subject to the availability of the vaccine.

(h) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:

1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;

2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;

3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and

4. Health care worker education programs which may include:

(i) Types of patient care activities that can result in hand contamination;

(ii) Advantages and disadvantages of various methods used to clean hands;

(iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and

(iv) Morbidity, mortality, and costs associated with health care associated infections.

(i) All hospitals 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.

(j) Each department of the hospital performing decontamination and sterilization activities must develop policies and procedures in accordance with the current editions of the CDC guidelines for "Prevention and Control of Nosocomial Diseases" and "Isolation in Hospitals".

(k) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including:

1. Receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing reusable items;

2. Assembling, wrapping, removal of outer shipping cartons, storage, distribution, and quality control of sterile equipment and medical supplies;

3. Proper utilization of sterilization process monitors, including temperature and pressure recordings, and use and frequency of appropriate chemical indicator or bacteriological spore tests for all sterilizers; and

4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies;

5. Procedures for recall and disposal or reprocessing of sterile supplies; and

6. Procedures for emergency collection and disposition of supplies and the timely notification of attending physicians, general medical staff, administration and the hospital's risk management program when special warnings have been issued or when warranted by the hospital's performance improvement process.

(l) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Sterile supplies may not be stored in their outermost shipping carton. This would include both hospital and commercially prepared supplies. Decontamination and preparation areas shall be separated.

(m) Space and facilities for housekeeping equipment and supply storage shall be provided in each hospital service area. Storage for bulk supplies and equipment shall be located away from patient care areas. Storage shall not be allowed in the outermost shipping carton. The building shall be kept in good repair, clean, sanitary and safe at all times.

(n) The hospital shall appoint a housekeeping supervisor who is qualified for the position by education, training and experience. The housekeeping supervisor shall be responsible for:

1. Organizing and coordinating the hospital's housekeeping service;

2. Acquiring and storing sufficient housekeeping supplies and equipment for hospital maintenance;

3. Assuring the clean and sanitary condition of the hospital to provide a safe and hygienic environment for patients and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and hospital policy; and

4. Verifying regular continuing education and competency for basic housekeeping principles.

(o) Laundry facilities located in the hospital shall:

1. Be equipped with an area for receiving, processing, storing and distributing clean linen;

2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;

3. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the hospital. Linen may not be stored in cardboard containers or other containers which offer housing for bugs; and,

4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.

(p) The hospital shall appoint a laundry service supervisor who is qualified for the position by education, training and experience. The laundry service supervisor shall be responsible for:

1. Establishing a laundry service, either within the hospital or by contract, that provides the hospital with sufficient clean, sanitary linen at all times;

2. Knowing and enforcing infection control rules and regulations for the laundry service;

3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures;

4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures; and,

5. Conducting periodic inspections of any contract laundry facility.

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

1. Any condition on the hospital site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

2. Cats, dogs or other animals shall not be allowed in any part of the hospital except

for specially trained animals for the handicapped and except as addressed by facility policy for pet therapy programs. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

3. A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.

4. Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.

5. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.

6. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.

(4) Nursing Services.

(a) The hospital must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times.

(b) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The chief nursing officer must be a licensed registered nurse who is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(c) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(d) There must be a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licenses.

(e) A registered nurse must assess, supervise and evaluate the nursing care for each patient.

(f) The hospital must ensure that an appropriate individualized plan of care is available for each patient.

(g) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. All nursing personnel assigned to special care units shall have specialized training and a program in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed, along with documentation of annual

competency skills.

(h) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:

1. The deceased was a patient at a hospital as defined by T.C.A. § 68-11-201(27);

2. Death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;

3. The nurse is licensed by the state; and

4. The nurse is employed by the hospital providing services to the deceased.

(i) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The chief nursing officer must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. Annual competency and skill documentation must be demonstrated on these individuals just as employees, if they perform clinical activities.

(j) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(k) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they must be:

1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and

2. Signed or initialed by the prescribing practitioner according to hospital policy.

(l) Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

(m) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(5) Medical Records.

(a) The hospital shall comply with the Tennessee Medical Records Act, T.C.A. §§ 68-11-301, et seq. A hospital shall transfer copies of patient medical records in a timely manner to requesting practitioners and facilities.

(b) The hospital must have a medical record service that has administrative responsibility for medical records. The service shall be supervised by a Registered Health Information Administrator (RHIA), a Registered Health Information Technician (RHIT), or a person qualified by work experience. A medical record must be maintained for every individual evaluated or treated in the hospital.

(c) The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing and retrieval of records.

(d) The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(e) All medical records, either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years, or for the period of minority plus one year for newborns, after which such records may be destroyed. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of its contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the hospital's policies and procedures, and no record may be destroyed on an individual basis.

~~(f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the department. Upon transfer to the department, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.~~

(f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the Tennessee Department of Health. Upon transfer to the Tennessee Department of Health, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.

(g) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.

(h) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with federal and state laws, court orders or subpoenas.

(i) The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(j) All entries must be legible, complete, dated and authenticated according to hospital policy.

(k) All records must document the following:

1. Evidence of a physical examination, including a health history, performed and/or updated no more than forty-five (45) days prior to admission or within forty-eight (48) hours following admission;

2. Admitting diagnosis;

3. Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

4. Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;

5. Properly executed informed consent forms for procedures and treatments specified by hospital policy, or by federal or state law if applicable, as requiring written patient consent;

6. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;

7. Discharge summary with outcome of hospitalization, disposition of case and plan for follow-up care; and

8. Final diagnosis with completion of medical records within thirty (30) days following discharge.

(l) Electronic and computer-generated records and signature entries are acceptable.

(6) Pharmaceutical Services.

(a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(b) A full-time, part-time or consulting pharmacist must be responsible for developing, supervising and coordinating all the activities of the pharmacy services.

(c) Current and accurate records must be kept of receipt and disposition of all scheduled drugs.

(d) Adverse drug events, both adverse reactions and medication errors, shall be reported according to established guidelines to the hospital performance improvement/risk management program and as appropriate to physicians, the hospital governing body and regulatory agencies.

(e) Abuses and losses of controlled substances must be reported, in accordance with federal and state laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(f) Current reference materials relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff in the pharmacy and in areas where medication is administered.

(g) Any unused portions of prescriptions shall be either turned over to the patient only on a written authorization including directions by the physician, or returned to the pharmacy for proper disposition by the pharmacist.

(h) Whenever patients bring drugs into an institution, such drugs shall not be administered unless they can be identified and ordered to be given by a physician.

(7) Radiologic Services.

(a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(b) The radiologic services must be free from hazards for patients and personnel.

(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) Radiologic services must be provided only on the order of practitioners with clinical privileges or of other practitioners authorized by the medical staff and the governing body to order the services.

(f) X-ray personnel shall be qualified by education, training and experience for the type of service rendered.

(g) All x-ray equipment must be registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health.

(h) 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.

(i) Patients must not be left unattended in pre- and post-radiology areas.

(8) Laboratory Services.

(a) The hospital must maintain, or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act. All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.

(b) Emergency laboratory services must be available 24 hours a day.

(c) A written description of services provided must be available to the medical staff.

(d) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(e) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(f) Laboratory services must be provided in keeping with services rendered by the hospital. This shall include suitable arrangements for blood and plasma at all times. Written policies and procedures shall be developed in concert with the Standards of American Association of Blood Banks. Documentation and record keeping shall be maintained for tracking and performance monitoring.

(9) Food and Dietetic Services.

(a) The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. A hospital may contract with an outside food management company if the company has a dietitian who serves the hospital on a full- time, part-time,

or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment. If an outside contract is utilized for management of its dietary services, the hospital shall designate a full-time employee to be responsible for the overall management of the services.

(b) The hospital must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:

1. A qualified dietitian; or,

2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,

3. An individual who has successfully completed in-person or online coursework that provided ninety (90) or more hours of classroom instruction in food service supervision. If the course has not been completed, this person shall be enrolled in a course and making satisfactory progress for completion within the time limit specified by the course requirement; or,

4. An individual who is a certified dietary manager (CDM), or certified food protection professional (CFPP); or,

5. A current or former member of the U.S. military who has graduated from an approved military dietary manager training program.

(c) There must be a qualified dietitian, full-time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the patient and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.

(d) There must be sufficient administrative and technical personnel competent in their respective duties.

(e) Menus must meet the needs of the patients.

1. Individual patient nutritional needs must be met in accordance with recognized dietary practices.

2. All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian to whom the physician who chairs the hospital's medical executive committee has referred this task. The medical staff and hospital's board of trustees shall decide the extent of ordering privileges that a qualified dietitian shall have and a mechanism to ensure that order writing by a qualified dietitian is coordinated with the responsible practitioner's care of the patient and complies with Tennessee law governing dietitians.

3. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

(f) Education programs, including orientation, on-the-job training, inservice education, and continuing education programs shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in personal hygiene, proper inspection, handling, preparation and serving of food and equipment.

(g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs.

~~(h) All food shall be from sources approved or considered satisfactory by the department and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.~~

(h) All food shall be from sources approved or considered satisfactory by the Commission and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.

(i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual."

(j) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.

(10) Critical Access Hospital.

(a) Every patient shall be under the care of a physician or under the care of a mid-level practitioner supervised by a physician.

(b) Whenever a patient is admitted to the facility by a mid-level practitioner, the supervising physician shall be notified of that fact, by phone or otherwise, and within 24 hours the supervising physician shall examine the patient or before discharge if discharged within 24 hours, and a plan of care shall be placed in the patient's chart, unless the patient is transferred to a higher level of care within 24 hours.

(c) A physician, a mid-level practitioner or a registered nurse shall be on duty and physically available in the facility when there are inpatients.

(d) A physician on staff shall:

1. Provide medical direction to the facility's health care activities and consultation for non-physician health care providers.

2. In conjunction with the mid-level practitioner staff members, participate in developing, executing, and periodically reviewing the facility's written policies and the services provided to patients.

3. Review and sign the records of each patient admitted and treated by a practitioner no later than fifteen (15) days after the patient's discharge from the facility.

4. Provide health care services to the patients in the facility, whenever needed and requested.

5. Prepare guidelines for the medical management of health problems, including

conditions requiring medical consultation and/or patient referral.

6. At intervals no more than two (2) weeks apart, be physically present in the facility for a sufficient time to provide medical direction, medical care services, and staff consultation as required.

7. When not physically present in the facility, either be available through direct telecommunication for consultation and assistance with medical emergencies and patient referral, or ensure that another physician is available for this purpose.

8. The physical site visit for a given two week period is not required if, during that period, no inpatients have been treated in the facility.

(e) A mid-level practitioner on staff shall:

1. Participate in the development, execution, and periodic review of the guidelines and written policies governing treatment in the facility.

2. Participate with a physician in a review of each patient's health records.

3. Provide health care services to patients according to the facility's policies.

4. Arrange for or refer patients to needed services that are not provided at the facility.

5. Assure that adequate patient health records are maintained and transferred as necessary when a patient is referred.

(f) The Critical Access Hospital, at a minimum, shall provide basic laboratory services essential to the immediate diagnosis and treatment of patients, including:

1. Chemical examinations of urine stick or tablet methods, or both (including urine ketoses);

2. Microscopic examinations of urine sediment;

3. Hemoglobin or hematocrit;

4. Blood sugar;

5. Gram stain;

6. Examination of stool specimens for occult blood;

7. Pregnancy test;

8. Primary culturing for transmittal to a CLIA certified laboratory;

9. Sediment rate; and,

10. CBC.

(11) Rural Emergency Hospital.

(a) A hospital shall be eligible to apply for a Rural Emergency Health ("REH") designation as such and conversion to a Rural Emergency Hospital, if the facility, as of December 27th, 2020, was a:

~~1. Critical Access Hospital as defined under Tenn. Comp. R. & Regs. 0720-14-~~

~~.01(19); or~~

1. Critical Access Hospital as defined under Tenn. Comp. R. & Regs. 0720-14-.01(26); or

2. General hospital with no more than 50 licensed beds located in an area designated by state or federal law as a rural area; or

3. General hospital with no more than 50 licensed beds located in an area designated as rural under 42 U.S.C. § 1395ww(d)(8)(E), or any successor statute.

(b) A facility applying for designation as a Rural Emergency Hospital shall include in its licensure application:

1. A detailed transition plan that lists the services that the facility will retain, modify, add, and discontinue.

~~2. A description of services that the facility intends to furnish on an outpatient basis pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(83)(b).~~

2. A description of services that the facility intends to furnish on an outpatient basis pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(101)(b).

3. A description of any additional services the hospital would be supporting, such as furnishing telehealth services and ambulance services, including operating the facility and maintaining the emergency department to provide such services covered by these rules.

4. Any such other information as the rules and regulations of the Health Facilities Commission may require.

(c) A Rural Emergency Hospital may be allowed to own and operate an entity that provides ambulance services.

(d) A licensed general hospital or Critical Access Hospital that applies for and receives licensure as a Rural Emergency Hospital and elects to operate as a Rural Emergency Hospital shall retain its original license as a general hospital or Critical Access Hospital. Such original license shall remain inactive while the Rural Emergency Hospital license is in effect.

(e) A licensed Rural Emergency Hospital may enter into any contracts required to be eligible for federal reimbursement as a Rural Emergency Hospital.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-3-511, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105; 42 U.S.C. § 1395x(kkk); and 42 U.S.C. § 1395cc(j).* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendment filed March 18, 2010; effective June 16, 2010. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed July 18, 2016; effective October 16, 2016. Amendments filed July 10, 2018; effective October 8, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022. Emergency rules filed December 27, 2022; effective through June 25, 2023. Emergency rules expired effective June 26, 2023, and the rules reverted to their previous statuses. Amendments filed August 11, 2023; effective November 9, 2023.*

**0720-14-.07 OPTIONAL HOSPITAL SERVICES.**

(1) Surgical Services.

(a) If the hospital provides surgical services, the services must be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

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

(c) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

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

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

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

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

(h) The health facilities commission shall publish an approved list of accredited surgical technology programs.

1. Surgical technologists must meet one (1) or more of the following:

(i) Successfully completed a nationally accredited surgical technology program, and holds and maintains certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission;

(ii) Successfully completed an accredited surgical technologist program;

(I) Has not, as of the date of hire, obtained certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission; and

(II) Obtains such certification no later than eighteen (18) months after completion of the program.

(iii) Successfully completed a training program for surgical technology in the armed forces of the United States, the national guard, or the United States public health service; or

(iv) Performed surgical technology services as a surgical technologist in a healthcare facility on or before May 21, 2007, and has been designated by the healthcare facility as being competent to perform surgical technology services based on prior experience or specialized training validated by competency in current practice. The healthcare facility employing or retaining such person as a surgical technologist under this subsection (a) obtains proof of such person's prior experience, specialized training, and current continuing competency as a surgical technologist and makes the proof available to the health facilities commission upon request of the commission.

2. This section does not prohibit a person from performing surgical technology services if the person is acting within the scope of the person's license, certification, registration, permit, or designation, or is a student or intern under the direct supervision of a healthcare provider.

~~(i) A hospital can petition the director of health care facilities of the department for a waiver from the provisions of 0720-14-.07(1)(h) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.~~

(i) A hospital can petition the Commission for a waiver from the provisions of 0720-14-.07(1)(h) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the Commission that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The Commission shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Commission.

(j) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal. Persons qualified to be employed as surgical technologists shall complete fifteen (15) hours of continuing education or contact hours annually. Current certification by the National Board of Surgical Technology and Surgical Assisting shall satisfy this requirement.

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

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

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

1. Call-in system;

2. Cardiac monitor;

3. Resuscitator;

4. Defibrillator;

5. Aspirator; and

6. Tracheotomy set.

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

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

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

(2) Anesthesia Services.

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

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

1. A qualified anesthesiologist;

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

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

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

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

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

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

2. An intraoperative anesthesia record;

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

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

(3) Nuclear Medicine Services.

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

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

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

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

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

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

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

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

1. Maintained in safe operating condition; and,

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

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

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

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

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

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

(4) Outpatient Services.

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

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

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

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

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

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

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

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

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

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

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

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

(5) Emergency Services.

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

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

1. The hospital's physical geographic boundaries; or

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

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

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

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

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

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

assess, stabilize, treat and/or transfer patients.

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

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

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

(h) Legend drugs in emergency rooms shall be stored in locked cabinets, except as otherwise provided for emergency drugs by the written policies and procedures of the hospital. Discharge medications may be dispensed to out-patients upon written physician orders provided that they have been packaged in containers by the pharmacist in amounts not to exceed twelve (12) hours dosage and labeled in accordance with Pharmacy Board rules.

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

1. Identification data;

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

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

4. Significant physical findings;

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

6. Treatment rendered;

7. Condition of the patient on discharge or transfer;

8. Diagnosis on discharge;

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

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

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

(6) Rehabilitation Services.

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

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

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

(d) Physical therapy, occupational therapy, speech therapy, or audiology services, if

provided, must be provided by staff who meet the qualifications specified by hospital policy, consistent with state law.

(e) Services must be furnished in accordance with a written plan of treatment in accordance with the practice acts of the practitioners who are authorized by medical staff to provide the services. The written plan of treatment must be incorporated in the patient's record.

(7) Obstetrical Services.

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

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

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

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

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

1. The name of the patient;

2. Her maiden name;

3. Date of delivery;

4. Sex of infant;

5. Name of physician;

6. Names of persons assisting;

7. What complications, if any, occurred;

8. Type of anesthesia used;

9. Name of person administering anesthesia; and

10. Other persons present.

(8) Pediatric Services.

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

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

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

(9) Respiratory Care Services.

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

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

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

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

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

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

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

(10) Social Work Services.

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

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

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

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

(11) Psychiatric Services.

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

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

(b) A hospital licensed by the Commission as a satellite hospital whose primary purpose is

the provision of mental health or substance abuse services, must verify to the Commission that Standards of the Department of Mental Health and Substance Abuse Services are satisfied.

(12) Alcohol and Drug Services.

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

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

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

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

(14) Burn Unit Services.

(a) If a hospital provides Burn unit services, the following licensing requirements apply:

1. 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. Patients shall not be admitted to the burn until a license has been issued. Applicants shall not hold themselves out to the public as being a burn unit until the license has been issued.

(i) The applicant shall allow the burn unit to be inspected by Commission staff. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action within ten (10) calendar days 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.

(ii) A provisional license shall be issued upon administrative approval of the initial application.

(iii) A provisional licensee must achieve American Burn Association (ABA) verification within five (5) years of obtaining a provisional license. A provisional licensee must comply with the following requirements:

(I) Provide the Commission with annual progress reports demonstrating engagement and measurable efforts toward obtaining verification.

(II) Provide data to the Burn Care Quality Platform (BCQP) and provide reports formatted in accordance with Commission reporting requirements.

(III) Participate in annual onsite visits conducted by Commission staff, consultant burn surgeons and burn nurses until ABA verification is

achieved.

I. Site visits must be scheduled by within twelve (12) months of provisional licensure.

II. Costs associated with site visits shall be assessed to the provisional licensee by the Commission through the issuance of an Assessment of Costs.

2. A full license shall not be issued until the facility is ABA verified and written confirmation verification has been achieved is submitted to the Commission.

3. A fully licensed burn unit must maintain ABA verification. Loss of ABA verification will cause the full license to be reverted to a provisional license until re-verification is achieved

(b) If a hospital provides Burn Unit services, the following administrative requirements apply:

1. The burn unit must have a Burn Unit Director who is responsible for the following:

(i) All burn unit administrative functions.

(ii) Creation of policies and procedures regarding burn unit care.

(iii) Ensure burn unit staff are properly credentialed through the general hospital's medical staff credentialing process.

(iv) Ensure burn unit staff obtain and maintain Advanced Burn Life Support (ABLS) certification.

2. The burn unit must have a Burn Nurse Leader who is responsible for the following:

(i) All burn unit nursing functions.

(ii) Ensure burn unit nurses obtain and maintain Advanced Burn Life Support (ABLS) certification.

(iii) Participate in burn unit quality improvement meetings.

(15) MRI Services

(a) If a hospital provides MRI services, the following licensing requirements apply to each unit:

1. Must become accredited by a nationally recognized and CMS approved accrediting organization within one year of licensure per machine and per diagnostic type.

2. Must adhere to all federal and state regulations.

(16) NICU Services

(a) If a qualifying hospital provides NICU services, the following licensing requirements apply:

1. 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. Patients shall not be admitted to the NICU until a license has been issued.

Applicants shall not hold themselves out to the public as being a NICU unit until the license has been issued.

(i) The applicant shall allow the NICU to receive an initial inspection by Commission staff. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action within ten (10) calendar days 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.

(ii) A provisional license shall be issued upon administrative approval of the initial application.

(iii) Within three (3) years of obtaining a provisional license, licensee must achieve either:

(I) State level verification; or

(II) Verification through the American Academy of Pediatrics (AAP).

(iv) Upon application, applicant will self-designate. At verification, licensee must comply with the corresponding requirements based upon level of designation (for levels II-IV) as illustrated in the referenced levels of care;

(I) The verification process shall be based upon the standards established by and referenced within the Tennessee Perinatal Care System, Guidelines for Regionalization, Hospital Care Levels, Staffing and Facility as published by the Tennessee Department of Health, Division of Family Health and Wellness. The Tennessee Perinatal Care System, Guidelines for Regionalization, Hospital Care Levels, Staffing and Facility shall be published by reference on the Health Facilities Commission website.

(b) Levels of Care – Neonatal Intensive Care Units II-IV Requirements:

1. Facility Capacity

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | Provide care for infants born at >32 weeks' gestation and weighing >1500 grams who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis. | E | E | E |
| (ii) | Provide mechanical ventilation for brief duration (<24 hours) and provide continuous positive airway pressure (CPAP). | E | E | E |
| (iii) | Stabilize infants born at <32 weeks' gestation and weighing <1500 grams until transfer to a neonatal intensive care facility. | E | E | E |
| (iv) | Provide care for infants who are convalescing after intensive care. | E | E | E |
| (v) | Provide sustained life support. | E | E | |
| (vi) | Provide comprehensive care for infants born <32 weeks gestation and weighing <1500 grams and infants born at all gestational ages and birth weights with critical illness. | E | E | |
| (vii) | Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists. | E | E | |
| (viii) | Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide. | E | E | |
| (ix) | Perform advanced imaging with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography. | E | E | |

| | | | | |
|---|---|---|---|---|
| (x) | Perform advanced imaging with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography. | E | E | |
| (xi) | Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions. | E | | |
| (xii) | Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site. | E | | |
| (xiii) | Facilitate transport. | E | | |

2. Education Services

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Educational services should include the following:** | | | |
| | All neonatal care providers should maintain both current NRP and S.T.A.B.L.E. provider status. The S.T.A.B.L.E. Cardiac Module is also recommended. | E | E | E |
| (ii) | **Parent Education** | | | |
| | Ongoing perinatal education programs for parents. | E | E | E |
| (iii) | **Nurses' Education** | | | |
| | Required to provide ongoing educational programs for their nurses that conform to the latest edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level IV, for neonatal nurses, published by the Tennessee Department of Health. Outreach educational activities are not required. | E | | |
| | Required to provide ongoing educational programs for their nurses that conform to the latest edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level III, for neonatal nurses, published by the Tennessee Department of Health. Outreach educational activities are not required. | | E | |
| | Programs for nurses that conform to the latest edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level II, for neonatal nurses, published by the Tennessee Department of Health. These neonatal courses should be made available periodically at Level II facilities by instructors on the staff of that institution and/or the staff from a Regional Perinatal Center. Courses may also transpire at a Regional Perinatal Center or at another site remote from the Level II hospital, thus requiring that the hospital provide nurses with educational leave for attendance. Level II hospitals are responsible for the necessary arrangements for nurse education. | | | E |
| (iv) | **Physicians' Education** | | | |
| | Level III & IV units are required to provide ongoing educational programs for physicians practicing in that institution. Outreach educational activities are not required. | E | E | |
| | For the Staff of the Regional Perinatal Center: A program of professional education must be maintained for the staff of the Regional Perinatal Center. These programs should satisfy the educational requirements for physicians, nurses, social workers, and others who function in the administration of Level III or Level IV care. | E | | |
| | For the Staff of Other Hospitals in the Region: The Regional Perinatal Center must maintain a program of professional outreach education for hospitals within its region. These programs of instruction require a staff of qualified educators to present ongoing courses to Level I, II, and III hospitals. These courses must satisfy the educational objectives set forth in the series of publications for the education of nurses and social workers published by the Tennessee Department of Health. | E | | |
| | Educational opportunities for physicians should be available upon request, provided by the instructional staff of the Regional Perinatal Center and by qualified individuals on the staff of the Level II institution. | | | E |
| (v) | **Site Visits** | | | |
| | The Regional Perinatal Center staff will engage in site visits upon request within its region. | E | | |

3. Neonatal Care

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Resuscitation** | | | |
| | Provision must be made for resuscitation of infants immediately after birth. Resuscitation capabilities should include assisted ventilation with blended oxygen administered by bag or T-piece resuscitator with mask or endotracheal tube, chest compression, and appropriate intravascular therapy. Refer to the most recent edition of the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program Guidelines for a complete list of resuscitation equipment and supplies. | E | E | |
| (ii) | **Transport from Delivery Room to the Special Care Nursery** | | | |
| | Transport to a special care nursery requires a capacity for uninterrupted support. An appropriately equipped pre-warmed transport incubator, with blended oxygen, should be used for this purpose. | E | E | |
| (iii) | **Transitional Care** | | | |
| | Recurrent observation of the neonate should be performed by personnel who can identify and respond to the early manifestations of neonatal disorders. | E | E | |
| (iv) | **Care of Sick Neonates** | | | |
| (I) | The care of moderately and severely ill infants entails the following essentials: | | | |
| | Continuous cardiorespiratory monitoring. | E | E | |
| | Serial blood gas determinations and non-invasive blood gas monitoring. | E | E | |
| | Periodic blood pressure determinations (intra-arterial when necessary). | E | E | |
| | Portable diagnostic imaging for bedside interpretation. | E | E | |
| | Availability of electrocardiograms and echocardiograms with rapid interpretation. | E | E | |
| | Laboratory Services: Clinical laboratory services must be available to fully support clinical neonatal functions. | E | E | |
| | Fluid and electrolyte management and administration of blood and blood components. | E | E | |
| | Phototherapy and exchange transfusion. | E | E | |
| | Administration of parenteral nutrition through peripheral or central vessels. | E | E | |
| | Provision of appropriate enteral nutrition and lactation support. | | | |
| (v) | **Mechanical Ventilatory Support** | | | |
| (I) | Unit must be qualified to provide mechanical ventilatory support. The essential qualifications are as follows: | | | |
| | Continuous in-house presence of personnel experienced in airway management, endotracheal intubation, and diagnosis and treatment of air leak syndromes. | E | E | |
| | A staff of nurses (R.N.) and respiratory therapists (R.T.) who are specifically educated in the management of neonatal respiratory disorders. | E | E | |
| | Blood gas determinations and other data essential to treatment must be available 24 hours a day, 7 days a week. | E | E | |
| | Level III nurseries should be able to provide a full range of respiratory support, including sustained conventional and/or high frequency ventilation and inhaled nitric oxide. | E | E | |
| (vi) | **Diagnostic Imaging** | | | |
| | Perform advanced imaging, with interpretation on an urgent basis, including CT, MRI, and echocardiography. | E | E | |
| (vii) | **Laboratory Services** | | | |
| | Clinical laboratory services must be available to fully support clinical neonatal functions. | E | E | |
| (viii) | **Transfusion Services** | | | |
| | Transfusion services must be maintained at all times. | | | |
| | An appropriately trained technician should be available in-house 24 hours a day, 7 days a week. | E | E | |

| | | | | |
|---|---|---|---|---|
| | All blood components must be obtainable on an emergency basis from within the facility. | E | _ | _ |
| | All blood components must be obtainable on an emergency basis, either on the premises or by pre-arrangement with another facility. | _ | E | _ |
| | Transfusion services should be maintained at all times. An appropriately trained technician should be in-house 24 hours a day, 7 days a week. All blood components must be available on an emergency basis, either on the premises or by pre-arrangement with another facility. | _ | _ | E |

4. Ancillary Services

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Laboratory Services:** | | | |
| | Clinical laboratory services must be available to fully support clinical neonatal functions. | E | E | _ |
| (I) | Laboratory capabilities should include but not be limited to the following: | _ | _ | _ |
| I. | **Routine Availability** | _ | _ | _ |
| | Clotting factors | E | E | E |
| | Serum total protein | E | E | E |
| | Serum total protein | E | E | E |
| | Serum albumin | E | E | E |
| | Serum IgM | E | E | E |
| | Serum triglycerides (for parenteral nutrition) | E | E | E |
| | Metabolic screen | E | E | E |
| | Liver function tests | E | E | E |
| | Serologic test for syphilis | E | E | E |
| | Serology for hepatitis | E | E | E |
| | Screening for HIV | E | E | E |
| | TORCH titers | E | E | E |
| | Viral cultures | E | E | E |
| II. | **Available 24 Hours - 7 Days a Week** | _ | _ | _ |
| | Hematocrit | E | E | E |
| | Hemoglobin | E | E | E |
| | Complete blood count | E | E | E |
| | Reticulocyte count | E | E | E |
| | Blood typing: major groups and Rh | E | E | E |
| | Cross match | E | E | E |
| | Minor blood group antibody screen | E | E | E |
| | Coombs' test | E | E | E |
| | Prothrombin time | E | E | E |
| | Partial thromboplastin time | E | E | E |
| | Platelet count | E | E | E |
| | Fibrinogen concentration | E | E | E |
| | Serum sodium, potassium, chloride | E | E | E |
| | Serum calcium | E | E | E |
| | Serum phosphorus | E | E | E |
| | Serum magnesium | E | E | E |
| | Serum blood glucose | E | E | E |
| | Therapeutic drug levels | E | E | E |
| | Serum bilirubin, total and direct | E | E | E |
| | Blood gases/pH | E | E | E |
| | Blood urea nitrogen | E | E | E |
| | Serum creatinine | E | E | E |
| | Serum/urine osmolalities | E | E | E |
| | Urinalysis | E | E | E |
| | Cerebrospinal fluid: cells, chemistry | E | E | E |

| | | | | |
|---|---|---|---|---|
| | Bacterial cultures and sensitivities | E | E | E |
| | C-reactive protein (CRP) | E | E | E |
| | Gram stain | E | E | E |
| | Toxicology | E | E | E |
| | Group B strep screening | E | E | E |

5. Consultation and Transfer

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Neonatal Transport:** | | | |
| | The Level IV facility that operates a transport service is required to maintain equipment and a trained team of personnel for the transport of newborn patients. The team and equipment must be available at all times. The Level IV facility is responsible for transport of referred infants with its own equipment, or alternatively, with equipment from a commercial source. | E | E | |
| | The Level IV facility that operates a transport service should originate a protocol that describes procedures, staffing patterns, and equipment for the transport of referred infants. The protocol should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health. | E | E | |
| | The Level IV facility that operates a transport service is required to maintain records of its activities. (See the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation.) | E | E | |
| | The Level II facility should maintain an active relationship with a Level III or Level IV facility in the region for consultation and transfer. Protocols for transport should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health. | | | E |
| | Neonatal Consultation and Transport: When the severity of an illness requires a level of care that exceeds the capacity of the Level II facility, the infant should be transferred to a Level III or Level IV institution capable of providing required care. Transfer of these infants should be provided after consultation with the receiving Level III or Level IV unit. Refer to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health, for more information. | | | E |
| (ii) | **Maternal-Fetal and Neonatal Transport** | | | |
| | The Regional Perinatal Center is responsible for maternal-fetal and neonatal transport described for Level III or Level IV facilities elsewhere in these Guidelines. Whereas the provision of these transport services is an option for Level III or Level IV units that do not function as Regional Perinatal Centers, transport services are required of a Regional Perinatal Center. Transport for the purpose of admission to the Regional Center must be made available to all patients within the state regardless of their financial status, and to patients referred from other Regional Perinatal Centers. Protocols for transport should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health. | E | | |
| | If no other appropriate facility is available to manage significant high-risk conditions, the Regional Perinatal Center must accept all such patients regardless of financial status. | E | | |
| | Telephone consultation by obstetric and newborn sub-specialists must be available to physicians and nurses within the region 24 hours a day, 7 days a week. | E | | |

6. Maintenance of Data

| | Requirement | IV | III | II |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| (i) | **Maintenance of Data and Assessment of Quality Measures** | | | |
| (I) | The following items represent the minimum information that should be in medical records maintained at Level II facilities: | | | |
| | Name, gender, hospital medical record number | E | E | E |
| | Date of birth | E | E | E |
| | Birthweight | E | E | E |
| | Gestational age | E | E | E |
| | Apgar scores | E | E | E |
| | Maternal complications (test results relevant to neonatal care; maternal illness potentially affecting the fetus; history of illicit substance use or any other known socially high-risk circumstances; complications of pregnancy associated with abnormal fetal growth, fetal anomalies, or abnormal results from tests of fetal well-being; information regarding labor and delivery; and situations in which lactation may be compromised) | E | E | E |
| | Discharge diagnoses | E | E | E |
| | Special care administered (specify) | E | E | E |
| | Documentation of newborn metabolic, hearing and critical congenital heart disease (CCHD) screens, and immunizations and medications given | E | E | E |
| | Bilirubin screen (according to American Academy of Pediatrics guidelines) | E | E | E |
| | Disposition<br>-Discharged home<br>-Transferred to a higher level of care / Receiving hospital / Transport service<br>-Expired | E | E | E |
| (II) | A systematic ongoing compilation of data should be maintained to reflect the care of sick patients, in addition to the listing of minimal data that is specified for Level I, Level II, and Level III facilities. All Level II & IV programs should participate in a state or national continuous quality improvement initiative that includes ongoing data collection and review for benchmarking and evaluation of outcomes. Examples of continuous quality improvement initiatives available in Tennessee are those provided by TIPQC and THA. | E | E | |
| (ii) | **Data Collection** | | | |
| | The Regional Perinatal Center must compile data (Program Objectives Report [POR]) on educational outreach that is performed as well as the region's analysis and evaluation of maternal and neonatal outcomes for quality improvement according to requirements prescribed by the Tennessee Perinatal Care System. These data are forwarded to a central facility on a regular basis. All Regional Perinatal Centers, if possible, should support clinical teams within the institution that are responsible for implementing State or National continuous quality improvement initiatives by providing advisory assistance, sharing data from the POR, disseminating information to the region, and/or aiding with financial support. | E | | |

7. Personnel Qualifications and Functions

| | Requirement | IV | III | II |
|---|---|---|---|---|
| (i) | **Physicians** | | | |
| (I) | **Director** | | | |
| | The director of the newborn intensive care unit must be a full-time, board-certified pediatrician with subspecialty certification in neonatal-perinatal medicine. The director is responsible for maintaining practice guidelines and, in cooperation with nursing and hospital administration, is responsible for developing the operating budget; evaluating and purchasing equipment; planning, developing, and coordinating in-hospital and outreach educational programs; and participating in the evaluation of perinatal care. | E | E | |
| | In a Level II hospital, a board-certified pediatrician with subspecialty certification in neonatal-perinatal medicine should be chief of the neonatal care service. The chief should assure that appropriate trained and adequate staff | | | E |

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| | are available at all times. | | | |
| (II) | **Neonatologists** | | | |
| | The attending physician for sick neonates must be fellowship-trained and board-certified or eligible to take the board certification exam in neonatal-perinatal medicine. | E | E | |
| | The co-directors of perinatal services should coordinate the hospital's perinatal care services and, in conjunction with other medical, anesthesia, nursing, respiratory therapy, and hospital administration staff, develop policies concerning staffing, procedures, equipment, and supplies. The medical directors of obstetrics and neonatology are responsible for setting the hospital's standard of perinatal care by working together to incorporate evidence-based practice patterns and nationally recognized care standards. | | | E |
| (III) | **Pediatricians** | | | |
| | A board-certified neonatologist must have primary and ultimate responsibility for infants who receive intensive care. Board-certified pediatricians, whose qualifications and appointments have been approved by the appropriate hospital committee, can care for infants who need more than routine care as long as they are under the supervision of a neonatologist. | E | E | |
| (IV) | **In-House Coverage** | | | |
| | In-house physician consultation and coverage should be provided 24 hours a day, 7 days a week by a board-certified neonatologist or a board-certified neonatal nurse practitioner. However, when in-house coverage does not include a board-certified neonatologist, he/she must be on-call and available to be on-site within 30 minutes of request. | E | E | |
| (V) | **Deliveries** | | | |
| | Deliveries of high-risk fetuses should be attended by an obstetrician and at least two other persons qualified in neonatal resuscitation whose only responsibility is the neonate. With multiple gestations, each newborn should have his or her own dedicated team of care providers who are capable of performing neonatal resuscitation according to the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program guidelines. | | | E |
| | Every delivery should be attended by at least one person whose primary responsibility is for the newborn and who is capable of performing neonatal resuscitation according to the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program guidelines. Either that person or someone else who is immediately available should have the skills required to perform a complete resuscitation, including endotracheal intubation and administration of medications. | E | E | E |
| | Deliveries of high-risk fetuses should be attended by an obstetrician and at least two other persons qualified in neonatal resuscitation whose only responsibility is the neonate. With multiple gestations, each newborn should have his or her own dedicated team of care providers who are capable of performing complete neonatal resuscitation according to the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program guidelines. | E | E | |
| (VI) | **Anesthesiologists** | | | |
| | Pediatric anesthesia services should be directed by a board-certified anesthesiologist who has a special interest and an expertise in pediatric anesthesia. | E | E | |
| (VII) | **Radiologists** | | | |
| | A radiologist must be available on-call at all times. | E | E | |
| (VIII) | **Sub-specialty Consultants** | | | |
| | Should have pediatric surgical sub-specialists on call and readily available for consultation and continuous patient management. | E | | |
| | Should be available on-site or at a closely related institution by prearranged consultative agreement, ideally in close geographic proximity. | | E | |

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| | Pediatric medical subspecialists | E | E | |
| | Pediatric surgical specialists | E | E | |
| | Pediatric anesthesiologists | E | E | |
| | Pediatric ophthalmologists | E | E | |
| (ii) | **Nurses** | | | |
| (I) | **The Nurse Manager** | | | |
| | Of the Level IV nursery should have completed education according to the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level IV, Neonatal, published by the Tennessee Department of Health. A baccalaureate degree is required. | E | | |
| | Of the Level III nursery should have completed education according to the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level III, Neonatal, published by the Tennessee Department of Health. A baccalaureate degree is required. | | E | |
| | The nurse manager (R.N.) is responsible for all nursing activities in the nurseries of Level II facilities. The nurse manager in a hospital with a Level II nursery must complete the Level II neonatal courses prescribed for staff nurses in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level II, published by the Tennessee Department of Health. | | | E |
| (II) | **Staff nurses (R.N.)** | | | |
| | Must have received courses as outlined in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level IV, for neonatal nurses, published by the Tennessee Department of Health. Nurses should maintain institutional unit-specific competencies. In addition, all nurses should be current NRP and S.T.A.B.L.E. providers. | E | | |
| | Must have received courses as outlined in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, Level III, for neonatal nurses, published by the Tennessee Department of Health. Nurses should maintain institutional unit-specific competencies. In addition, all nurses should be current NRP and S.T.A.B.L.E. providers. | | E | |
| | Must be skilled in the observation and treatment of sick infants. For Level II facilities, they must complete the Level II neonatal course for nurses outlined in the most recent edition of the Tennessee Perinatal Care System Educational Objectives for Nurses, published by the Tennessee Department of Health. Nurses should maintain institutional unit-specific competencies. In addition, all nurses should be current NRP and S.T.A.B.L.E. providers. | | | E |
| (III) | **Nurse Educator** | | | |
| | Should have at least one neonatal nurse on its full-time staff who is responsible for staff education. This nurse should either be masters' prepared or actively pursuing an advanced degree. | E | E | |
| (IV) | **Recommended Registered Nurse (R.N.) / Patient Ratios for Newborn Care (Association of Women's Health, Obstetric, and Neonatal Nurses Guidelines for Professional Registered Nurse Staffing for Perinatal Units, 2010):** | | | |
| | 1:5-6 Newborns requiring only routine care | | | E |
| | 1:3-4 Newborns requiring continuing care | | | E |
| | 1:2-3 Newborns requiring intermediate care | E | E | E |
| | 1:1-2 Newborns requiring intensive care | E | E | E |
| | 1:1 Newborns requiring multisystem support | E | E | E |
| | 1 or more :1 Unstable newborns requiring complex critical care | E | E | E |
| (iii) | **Social Workers** | | | |
| | The services of social workers should be made available by the hospital 24 hours a day, 7 days a week. These services should be provided by a staff that is qualified in perinatal social work. This requires that social workers be educated according to the most recent edition of the Tennessee Perinatal Care System Educational Objectives in Medicine for Perinatal Social Workers, | E | E | |

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| | published by the Tennessee Department of Health. | | | |
| (iv) | **Case Manager / Discharge Coordinator** | | | |
| (I) | **Case Manager / Discharge Coordinator** | | | |
| | Personnel experienced in dealing with discharge planning and education, follow-up and referral, and home care planning should be available to neonatal intensive care unit staff members and families. | E | E | |
| | Personnel experienced in dealing with perinatal issues, discharge planning and education, follow-up and referral, home care planning, and bereavement support should be available to intermediate and intensive care unit staff members and families. | | | E |
| (II) | **Post-discharge Maternal Follow-up** | | | |
| | Follow-up evaluation of selected women who are discharged from the Regional Perinatal Center should be arranged. | E | | |
| (III) | **Post-discharge Neonatal Follow-up** | | | |
| | Follow-up evaluation of selected infants who are discharged from the Regional Perinatal Center should be performed. Neonatal intensive care unit graduates who are considered high risk and those with birthweights <1500 grams should be enrolled in an organized follow-up program that tracks and records medical and neurodevelopmental outcomes to allow later analysis. | E | | |
| (v) | **Respiratory Therapists** | | | |
| | Respiratory therapists who can provide supplemental oxygen, assisted ventilation and continuous positive pressure ventilation (including high flow nasal cannula) of neonates with cardiopulmonary disease should be continuously available on-site to provide ongoing care as well as to address emergencies. | | | E |
| | Dedicated respiratory therapists who can provide the assisted ventilation of neonates with cardiopulmonary disease must be available. The nursery's respiratory therapy director must be a registered respiratory therapist (R.R.T.). | E | E | |
| (vi) | **Dietitian / Lactation Consultant** | | | |
| | The staff must include at least one dietitian who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk neonates. Availability of lactation consultants 7 days a week is recommended to assist with complex breastfeeding issues. 1.6 full-time equivalent lactation consultants are recommended for every 1,000 births based on annual birth volume in Level II perinatal facilities (Association of Women's Health, Obstetric, and Neonatal Nurses Guidelines for Professional Registered Nurse Staffing for Perinatal Units, 2010). | | | E |
| | The staff must include at least one dietitian who is knowledgeable in the management of parenteral and enteral nutrition of low birthweight and other high-risk infants. Availability of lactation consultants 7 days a week is recommended to assist with complex breastfeeding issues. 1.9 full-time equivalent lactation consultants are recommended for every 1,000 births based on annual birth volume in Level III (also applies to Level IV) perinatal facilities (Association of Women's Health, Obstetric, and Neonatal Nurses Guidelines for Professional Registered Nurse Staffing for Perinatal Units, 2010). | E | E | |
| (vii) | **Pharmacist** | | | |
| | A registered pharmacist with expertise in compounding and dispensing medications, including total parenteral nutrition (TPN) for neonates must be available 24 hours a day, 7 days a week. | | | E |
| | A registered pharmacist with expertise in compounding and dispensing medications for neonates must be included on staff. Registered pharmacists with expertise in dispensing neonatal medications, including total parenteral nutrition (TPN), must be available 24 hours a day, 7 days a week. | E | E | |
| (viii) | **Occupational Therapist / Physical Therapist / Speech Therapist** | | | |
| | At least one occupational therapist or physical therapist and one speech | E | E | |

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| | therapist with neonatal expertise must be included on staff. These disciplines will work collaboratively with the medical and nursing staffs to provide developmentally appropriate care. | | | |
| (ix) | **Neonatal Follow-up Services** | | | |
| | Neonatal intensive care unit graduates who are considered high risk and those with birthweights <1500 grams should be enrolled in an organized follow-up program that tracks and records medical and neurodevelopmental outcomes to allow later analysis. | E | E | |

8. Space and equipment for level II Facilities

| | Requirement | IV | III | II |
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| (i) | **Physical facilities and equipment** | | | |
| | Physical facilities and equipment should meet criteria published in the latest edition of the Guidelines for Perinatal Care, jointly published by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. | | | E |
| | Equipment in the intensive care nursery of a Level III or IV facility should be adequate for the care of moderately and severely ill infants in accordance with contemporary standards. The quantities of all items of equipment should be sufficient to support the management of the maximum number of infants that are anticipated at times of peak census loads. An in-house Bioengineering Department should have an active program for preventive maintenance and rapid repair. | E | E | |
| (ii) | **Minimal equipment for care of the normal infant includes:** | | | |
| (II) | **Minimal equipment for care of the normal infant includes:** | | | |
| | A platform scale, preferably with metric indicators. | E | E | E |
| | A controlled source of continuous and/or intermittent suction. | E | E | E |
| | Incubators and/or radiant warmers for adequate thermal support. | E | E | E |
| | Equipment for determination of blood glucose at the bedside. | E | E | E |
| | Ability to provide intensive phototherapy. | E | E | E |
| | A device for the external measurement of blood pressure from the infant's arm or thigh. | E | E | E |
| | Oxygen flow meters, tubing, binasal cannulas for short-term administration of oxygen. | E | E | E |
| | A headbox assembly (oxygen hood), an oxygen blending device, and warming nebulizer for short-term administration of oxygen. | E | E | E |
| | An oxygen analyzer that displays the ambient concentration of oxygen. | E | E | E |
| | A newborn pulse oximeter for non-invasive blood oxygen monitoring. | E | E | E |
| | An infusion pump that can deliver appropriate volumes of continuous fluids and/or medications for newborns. | E | E | E |
| | A fully equipped neonatal resuscitation cart. | E | E | E |
| | Positive pressure ventilation equipment and masks; endotracheal tubes in all the appropriate sizes for neonates. | E | E | E |
| | A laryngoscope with premature and infant size blades. | E | E | E |
| | A CO2 detector. | E | E | E |
| | Laryngeal mask airway (LMA, size 1) | E | E | E |
| (II) | **Intermediate Care Nursery** | | | |
| | Additional equipment needed for intermediate care newborns includes: | E | E | E |
| | A servo-controlled incubator or heated open bed for each infant who requires a controlled thermal environment. | E | E | E |
| | Cardiorespiratory monitors that include pressure and waveform monitoring. | E | E | E |
| | Oxygen analyzers, blenders, heaters, and humidifiers sufficient for anticipated census. | E | E | E |
| | A sufficient number of headbox assemblies (oxygen hoods). | E | E | E |
| | Modes of respiratory support: binasal cannulas, conventional mechanical ventilator, mechanism to deliver nasal CPAP. | E | E | E |

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| | A bag or t-piece resuscitator and mask for each infant. | E | E | E |
| | An adequate supply of endotracheal tubes and other intubation supplies and LMA. | E | E | E |
| | A device for viewing x-rays in the infant area. | E | E | E |

(c) If a hospital provides NICU services the following administrative requirements apply:

1. The NICU must have a NICU Director who is responsible for the following:

(i) All NICU administrative functions;

(ii) Creation of policies and procedures regarding NICU care;

(iii) Ensure NICU staff are properly credentialed through the general hospital's medical staff credentialing process; and

(iv) Any other requirements in 0720-48-.02.

2. The NICU must have a Nurse Manager who is responsible for all NICU nursing functions.

(d) A NICU patient qualifying for lvl III care may be able to receive lvl II care services and continue as a patient if the patient's treating physician certifies that such care can be appropriately provided in the lvl II NICU.

(17) PET Services

(a) If a hospital provides PET services, the following licensing requirements apply:

1. Each PET unit must become accredited by a nationally recognized and CMS approved accrediting organization within one year of licensure per machine and per diagnostic type.

(b) All PET units must adhere to all federal and state regulations.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-209, 68-57-101, 68-57-102, 68-57-104, and 68-57-105.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed June 12, 2003; effective August 26, 2003. Amendment filed July 27, 2005; effective October 10, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendments filed July 10, 2018; effective October 8, 2018. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.08 BUILDING STANDARDS.**

(1) A hospital shall construct, arrange, and maintain the condition of the physical plant and the overall hospital environment in such a manner that the safety and well-being of the patients are assured.

~~(2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including~~

~~referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.~~

(2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the Commission. All facilities shall conform to the current edition of the following applicable codes as approved by the Commission: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.

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

(4) A licensed contractor shall perform all new construction and renovations to hospitals, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in hospitals, including the submission of phased construction plans and the final drawings and the specifications to each.

~~(5) No new hospital shall be constructed, nor shall major alterations be made to an existing hospital without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new hospital is licensed or before any alteration or expansion of a licensed hospital can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.~~

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

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

~~(7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the department requires.~~

(7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the Commission may require. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the Commission requires.

~~(a) The project architect or engineer shall forward two (2) sets of plans to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the owner's understanding that such work is at the owner's own risk and without assurance that final approval of final plans and specifications shall be granted. The project architect or engineer shall submit final plans and specifications for review and approval. The department must grant final approval before the project proceeds beyond foundation work.~~

(a) The project architect or engineer shall forward two (2) sets of plans to the Commission for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the owner's understanding that such work is at the owner's own risk and without assurance that final approval of final plans and specifications shall be granted. The project architect or engineer shall submit final plans and specifications for review and approval. The commission must grant final approval before the project proceeds beyond foundation work.

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

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

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

(10) Architectural drawings shall include where applicable:

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

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

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

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

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

(j) Code analysis.

(11) Structural drawings shall include where applicable:

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

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

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

(12) Mechanical drawings shall include where applicable:

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

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

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

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

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

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

(13) Electrical drawings shall include where applicable:

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

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

(c) An electrical system that complies with applicable codes;

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

(e) Circuit breakers that are properly labeled; and

(f) Ground-Fault Circuit Interrupters (GFCI) that are required in all wet areas, such as kitchens, laundries, janitor closets, bath and toilet rooms, etc, and within six (6) feet of any lavatory.

(14) The electrical drawings shall not include knob and tube wiring, shall not include electrical cords that have splices, and shall not show that the electrical system is overloaded.

(15) In all new facilities or renovations to existing electrical systems, the installation must be approved by an inspector or agency authorized by the State Fire Marshal.

(16) Sprinkler drawings shall include where applicable:

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

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

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

~~(17) The licensed contractor shall not install a system of water supply, plumbing, sewage, garbage or refuse disposal nor materially alter or extend any existing system until the architect or engineer submits complete plans and specifications for the installation, alteration or extension, to the department demonstrating that all applicable codes have been met and the department has granted necessary approval.~~

(17) The licensed contractor shall not install a system of water supply, plumbing, sewage, garbage or refuse disposal nor materially alter or extend any existing system until the architect or engineer submits complete plans and specifications for the installation, alteration or extension, to the Commission demonstrating that all applicable codes have been met and the Commission has granted necessary approval.

(a) Before the hospital is used, Tennessee Department of Environment and Conservation shall approve the water supply system.

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

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

(18) It shall be demonstrated through the submission of plans and specifications that in each hospital:

(a) 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;

(b) Rooms and areas containing radiation producing machines or radioactive material must have primary and/or secondary barriers to assure compliance with Regulations for Protection Against Radiation and security for materials. Radiation material shall be required to be stored and security must be provided in accordance with federal and state regulations to prevent exposure of the material to theft or tampering.

(19) When constructing new facilities or during major renovations to the operating suites, the hospital shall ensure that male and female physicians and staff have equitable proportional locker facilities including equal equipment, and similar amenities, with equal access to uniforms. Existing hospitals shall strive to have equitable male and female facilities. If physical changes are required, the additional areas shall maintain the flow and divisions in the sterile environments.

~~(20) The department shall acknowledge that it has reviewed plans and specifications in writing with copies sent to the project architect, the project engineer, the owner, the manager or other executive of the institution. The department may modify the distribution of such review at its discretion.~~

(20) The Commission shall acknowledge that it has reviewed plans and specifications in writing with copies sent to the project architect, the project engineer, the owner, the manager or other

executive of the institution. The Commission may modify the distribution of such review at its discretion.

~~(21) In the event submitted materials do not appear to satisfactorily comply with 0720-14-.08(2), the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.~~

(21) In the event submitted materials do not appear to satisfactorily comply with 0720-14-.08(2), the Commission 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.

(22) The licensed contractor shall execute all construction in accordance with the approved plans and specifications

~~(23) If construction begins within one hundred eighty (180) days of the date of department approval, the department's written notification of satisfactory review constitutes compliance with 0720-14-.08(2). This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.~~

(23) If construction begins within one hundred eighty (180) days of the date of Commission approval, the Commission's written notification of satisfactory review constitutes compliance with 0720-14-.08(2). This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

~~(24) Prior to final inspection a CD Rom disc, in TIF or PDF format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.~~

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

~~(25) The department requires the following alarms that shall be monitored twenty-four (24) hours per day:~~

(25) The Commission requires the following alarms that shall be monitored twenty-four (24) hours per day:

(a) Fire alarms;

(b) Generators (if applicable); and

(c) Medical gas alarms (if applicable).

(26) Each hospital shall ensure that an emergency keyed lock box is installed next to each bank of functioning elevators located on the main level. Such lock boxes shall be permanently mounted seventy-two inches (72") from the floor to the center of the box, be operable by a universal key no matter where such box is located, and shall contain only fire service keys and drop keys to the appropriate elevators.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 68-11-261.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed February 18, 2003; effective May 4, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007. Repeal and new rule*

*filed December 20, 2011; effective March 19, 2012. Amendment filed January 21, 2016; effective April 20, 2016. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.09 LIFE SAFETY.**

~~(1) Any hospital 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.~~

(1) Any hospital 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 hospital 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. Fire drills shall be held at least quarterly for each work shift for hospital personnel in each separate patient-occupied hospital building. There shall be a written report documenting the evaluation of each drill and the action recommended or taken for any deficiencies found. Records which document and evaluate these drills must be maintained for at least three (3) years. 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.~~

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***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendments filed September 6, 2005; effective November 20, 2005. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.10 INFECTIOUS WASTE AND HAZARDOUS WASTE.**

(1) Each hospital 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, waste from the production of biologicals, discarded live and attenuated vaccines, 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 surgery and autopsy;

(e) All discarded sharps (e.g., 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; and

(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 storage, 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 or stored 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 disinfected each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable fluid resistant liners or other devices removed with the waste; and

(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) Infectious 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; and

(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.

(c) Outside containers should have a biohazard label conspicuously identified.

(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 waste 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 waste shall be stored, transported, and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily cleanable material and shall be kept on elevated platforms.

***Authority:*** *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.11 RECORDS AND REPORTS.**

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

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

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

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

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

(b) An Acknowledgment of Paternity Form provided by the Tennessee Department of Health; and

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

~~(4) A report of fetal death shall be completed by the hospital for each dead fetus delivered where the fetus weighs three hundred fifty (350) grams or more, or in the absence of weight, is of~~

~~twenty (20) completed weeks of gestation or more. The report shall be in a form or format approved by the State Registrar and shall be submitted to the department's Office of Vital Records within ten (10) days of the delivery.~~

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

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

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

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

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

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

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

(8) The hospital shall report all incidents of abuse, neglect, and misappropriation to the

Commission in accordance with T.C.A. § 68-11-211.

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

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

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

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

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

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

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

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

(11) The hospital shall report, at least quarterly to the Commission, claims data on the UB-04 form or its successor for all discharges from the facility.

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

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

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

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

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

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

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

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

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

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

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

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

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

(g) Orders of the Commission, if any;

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

(i) Maintenance records of all safety equipment.

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-3-102, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-310.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007. Amendments filed January 3, 2012; effective April 2, 2012. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.12 PATIENT RIGHTS.**

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

(a) To privacy in treatment and personal care;

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

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

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

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

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

maker. The hospital must have policies to govern access and duplication of the patient's record;

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

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

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

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

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendments filed September 6, 2005; effective November 20, 2005. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.**

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

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

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

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

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

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the 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) 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 0720-14-.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 0720-14-.13(16)(c) through 0720-14-.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 0720-14-.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 0720-14-.13(20) through 0720-14-.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 0720-14-.13(20) through 0720-14-.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) Physician Orders for Scope of Treatment (POST)

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

1. With the informed consent of the patient;

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

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

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

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

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

3. Either:

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

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

4. Either:

(i) With the informed consent of the patient;

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

(iii) If the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act, is not reasonably available and such authority to issue is contained in the physician assistant, nurse practitioner or clinical nurse specialist's protocols and the physician assistant or nurse determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

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

~~(d) A POST issued in accordance with this section shall remain valid and in effect until revoked in accordance with this rule and applicable regulations, qualified emergency medical services personnel; and licensed health care practitioners in any facility, program, or organization operated or licensed by the Board for Licensing Health Care Facilities, the Department of Mental Health and Substance Abuse Services, or the Department of Intellectual and Developmental Disabilities, or operated, licensed, or owned by another state agency, shall follow a POST that is available to such persons in a form approved by the Board for Licensing Health Care Facilities~~

(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

(Rule 0720-14-.15, continued)

arrest in accordance with accepted medical practices. This action shall have no application to any do-not-resuscitate order that is not a POST, as defined in these rules.

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

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-224, and 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 7, 2007; effective April 23, 2007. Amendments filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.14 DISASTER PREPAREDNESS.**

(1) Emergency Electrical Power.

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

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

(c) The emergency power system shall have a minimum of twenty-four (24) hours of either propane, natural gas, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the hospital shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month. Records shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every hospital shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills.

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients to other health care facilities must have written agreements for emergency transfers. Their agreements may be mutual, i.e. providing for transfers either way.

(Rule 0720-14-.15, continued)

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to all staff. Provisions that have security implications may be omitted from the outline versions. Familiarization information shall be included in employee orientation sessions and more detailed instructions must be included in continuing education programs. Records of orientation and education programs must be maintained for at least three (3) years.

4. Drills of the disaster preparedness plan shall be conducted at least once a year. The risk focus may vary by type of drill. Drills are for the purpose of educating staff, resource determination, testing personal safety provisions and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

5. As soon as possible, real situations that result in a response by local authorities must be documented. This includes a critique of the activation of the plan. Actual documented situations that had education and training value may be substituted for a drill.

(b) Community Emergency (Mass Casualty).

1. Every hospital, unless exempted due to its limited scope of clinical services, shall have a plan that provides for the reception and treatment, within its capabilities, of medical emergencies resulting from a disaster within its usual service area. The plan should consider the probability of the types of disasters which might occur, both natural and “man-made”.

2. The plan must provide for additional staffing, medical supplies, blood and other resources which would probably be needed. The plan must also include for the deferral of elective admission patients and also for the early transfer or discharge of some current patients if it appears that the number of casualties will exceed available staffed beds.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to staff who would be assigned non-routine duties during these types of emergencies. Familiarization information shall be included in employee orientation sessions and more detailed instruction must be included in continuing education programs. Records of orientation and education must be maintained for at least three (3) years.

4. At least one drill shall be conducted each year for the purpose of educating staff, resource determination, and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

5. As soon as possible, actual community emergency situations that result in the treatment of more than twenty (20) patients, or fifteen percent (15%) of the licensed bed capacity, whichever is less, must be documented. Actual situations that had education and training value may be substituted for a drill. This includes documented actual plan activation during community emergencies, even if no patients are received.

(c) Emergency Planning with Local Government Authorities.

1. All hospitals shall establish and maintain communications with the county

(Rule 0720-14-.15, continued)

Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The facility shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

2. Each hospital must rehearse both the Physical Facility and Community Emergency plan as required in these regulations, even if the local Emergency Management Agency is unable to participate.

3. A file of documents demonstrating communications and cooperation with the local agency must be maintained.

***Authority:*** *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

**0720-14-.15 APPENDIX I**

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

| | |
|---|---|
| Tennessee Physician Orders for Scope of Treatment<br>(POST, sometimes called "POLST")<br><br>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<br><br>First Name/Middle Initial<br><br>Date of Birth |

| | |
|---|---|
| **Section A**<br>*Check One Box Only* | **CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse and is not breathing.**<br>☐ **Resuscitate(CPR)** ☐ **Do Not Attempt Resuscitation (DNR / no CPR) (Allow Natural Death)**<br>When not in cardiopulmonary arrest, follow orders in **B, C,** and **D.** |
| **Section B**<br><br>*Check One Box Only* | **MEDICAL INTERVENTIONS. Patient has pulse and/or is breathing.**<br><br>☐ **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.**<br><br>☐ **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.**<br><br>☐ **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.**<br><br>*Other Instructions:*_____ |
| **Section C**<br>*Check One* | **ARTIFICIALLY ADMINISTERED NUTRITION. Oral fluids & nutrition must be offered if feasible.**<br>☐ No artificial nutrition by tube.<br>☐ Defined trial period of artificial nutrition by tube.<br>☐ Long-term artificial nutrition by tube.<br><br>*Other Instructions:*_____ |

(Rule 0720-14-.15, continued)

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

| **Physician/NP/CNS/PA Name (Print)** | **Physician/NP/CNS/PA Signature Date**<br><br>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 |
| | | | |

(Rule 0720-14-.15, continued)

**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.

(Rule 0720-14-.15, continued)

(2) Advance Directive for Health Care Form.

**ADVANCE DIRECTIVE FOR HEALTH CARE***
(Tennessee)

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

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

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

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

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

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

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

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

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

| | |
|---|---|
| ☐ 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. |

(Rule 0720-14-.15, continued)

| | |
|---|---|
| ☐ 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

(Rule 0720-14-.15, continued)
is personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who signed as the "patient." The patient personally appeared before me and signed above or acknowledged the signature above as his or her own. I declare under penalty of perjury that the patient appears to be of sound mind and under no duress, fraud, or undue influence.

My commission expires: _____ _____
Signature of Notary Public

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

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

***Authority:*** *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-11-224, and 68-11-1805.* ***Administrative History:*** *Original rule filed February 16, 2007; effective May 2, 2007. Repeal and new rule filed August 28, 2012; effective November 26, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendments filed February 8, 2017; effective May 9, 2017. Transferred from chapter 1200-08-01 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

Recommended to be added as section 0720-14-.07(16)(e)

(16) NICU Services

(e) Quality Assurance Program Participation- Each licensed NICU shall annually participate in a neo-natal quality assurance program approved by the Commission.

1. Approval of Quality Assurance Programs- Each program seeking approval by the Commission shall submit the following in writing:

   (i) Curriculum Vitae of each presenter or program leader.

   (ii) Copies of programmatic material to be used during the program.

   (iii) Information concerning the neonatal subject to be covered by the program, as well as the anticipated length of the program.

   (iv) Information on how annual participation and/or completion shall be documented by the program, which shall include a blank copy of any certificate to be used.

2. The Commission shall maintain a list of approved quality assurance programs.

3. Each licensed NICU must maintain, and make readily available for inspection by Commission staff, participation or completion certificates for the preceding three (3) years.

4. If no Quality Assurance Program has been approved by the Commission for any calendar year, this requirement shall be automatically waived.


June 13, 2025

Mr. Logan Grant, Executive Director
Members of the Commission
Health Facilities Commission
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Dear Director Grant and Members of the Health Facilities Commission:

We write today to share our concerns with the proposed rules for Neonatal Intensive Care Units (NICUs), with a notice ID of 4043 and file date April 25, 2025.

For more than twenty years, the Children's Hospital Alliance of Tennessee (CHAT) has advocated for quality standards of care for Tennessee children. Our member hospitals each maintain the highest-level NICU designation operating in their respective regions. Our NICUs receive critically ill newborns for advanced care. Our hospitals serve throughout a child's life as centers for specialty pediatric care committed to the long-term health needs of all Tennessee children.

Our alliance helped to identify and recruit pediatric specialists required to appropriately develop these guidelines to meet the legislature's intent. We ensured representation within the Commission's Technical Advisory Group (TAG) of board-certified obstetricians, neonatologists, nurse leaders, administrators and quality leaders. Our members and others from across the Tennessee health care community devoted significant time over the past ten months to this process.

**Our key concern is the lack of specificity related to the requirements for quality.** In 2024 the legislature made clear in its charge to the Commission that quality was a requirement of licensure. The rules as published do not meet the legislative intent nor do they fully incorporate the suggestions of the NICU-TAG with respect to quality. We urge the Commission's attention to this oversight through adopting language consistent with written proposals to staff, such as:

*All NICUs shall demonstrate a commitment to evidence-based practice through active participation in a quality initiative each time they are verified or reverified. Level III and Level IV NICUs will submit proof of their active participation by providing documentation from the quality initiative organization at the time of their license verification or re-verification. The Perinatal Advisory Committee will maintain a list of quality initiative programs that will meet the licensure quality requirement.*

Secondarily, the rules published do not incorporate many of the technical corrections supplied by the TAG to Commission staff to properly align the proposed rules with existing state and national standards and to accurately reflect the role of the Perinatal Regional Centers. We believe that some of this is timing due to the rule making process – the TAG met following the publication of the draft dated April

25, 2025 to share their feedback with staff.

Building on the strong collaborative work of the TAG, we want to continue to urge the Commission and the State of Tennessee to invest in additional personnel with experience in developing quality programs in the hospital setting to draft, evaluate, and enforce the quality standards recommended by experts who served on the TAG.

Exhibit A to this letter provides a detailed list of suggested changes to align with state guidelines.

It is our recommendation that prior to final approval the Commission receives written confirmation from the State of Tennessee's expert in this field, the Clinical Co-Chair of the Perinatal Advisory Council, attesting that the technical corrections and alignment to existing state guidelines have been properly incorporated and that the quality standards are clearly articulated before the Commission takes action to adopt final rules for NICU licensure.

We offer these suggestions in the spirit of ensuring that the Health Facilities Commission NICU Quality Standards will be known and accepted by Tennessee families as a measure they can trust. We want these standards to be clearly aligned with existing state and national best practices and to, as required by law, incorporate meaningful quality measures.

With clear and high-quality standards, we believe every baby in Tennessee requiring NICU care will have a better chance to not only survive, but to thrive.

Sincerely,

Alice L. Rolli

Alice Rolli
Executive Director
The Children's Hospital Alliance of Tennessee
Children's Hospital at Erlanger
East Tennessee Children's Hospital
Le Bonheur Children's Hospital
Monroe Carell Jr. Children's Hospital at Vanderbilt
Niswonger Children's Hospital

**Addenda A:**

**Page numbers provided correspond to the page numbers within the marked up draft of the HFC document:**
https://www.tn.gov/content/dam/tn/hfc/documents/HFC-Rules_SS-7037%200720-14_Signed_stamped.pdf

**p. 8**
**66, Neonatal Care Units.**

The term Nursery should be updated to Neonatal Intensive Care Unit (NICU).

Part B should reflect the same verbiage as Part C with respect to referencing the capabilities of the lower-level unit.

"Level III neonatal intensive care units (NICUs) include the capabilities of Level II units with additional capabilities including" (continue with reference of draft language - [the ability to care for infants who are born at <=32 weeks....])

**p. 9**
**78, Perinatal Advisory Committee (PAC).**

The commission staff is encouraged to review the requirements for the PAC found in TCA 68-1-803. There is a requirement of a public health representative, but no mention of the requirement of the Title V Director. This should be revised to be consistent with state law.

**p. 10**
**90, Program Objective Report (POR).**
This term appears to be used exclusively with discussion of Perinatal Regional Centers and is unclear (p. 16. B. 6.ii) if the Commission is envisioning the centers as managing quality oversight on behalf of the Commission or if the rules are suggesting that the Centers become separately licensed.
**and**
**p.58.b.6.ii. Maintenance of Data and Data Collection**
These definitions and sections should be revised following consultation with TDH leadership for the Perinatal Advisory Committee. A perinatal regional center is not required to maintain a specific NICU designation – a level IV facility may not be a regional center (as is currently the case). This section should be reviewed to clarify what role the HFC is expecting the Perinatal Centers to assume with respect to data collection for quality standards and that role in ongoing licensure for NICUs.

**p. 13**
**0720-14-.02 LICENSING PROCEDURES.**
"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 hospital or any of the following optional services: Burn Unit, MRI Unit, NICU, or PET Unit 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 and become invalid annually on the anniversary date of their original issuance."

Clarity may be needed within this section or elsewhere in the document – specifically at p. 53, 16 (a) 1 with respect to outlining the process for existing NICUs to continue to operate, the role of the annual license fee, and how these fit with the three-year re-certification timeline. This suggestion is also addressed below (p.53).

**p. 19**

**0720–14-.04 Administration (6)**

"No hospital 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 hospital 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."

This section may need to be updated to include the Tennessee Department of Children's Services role in receiving reports for abuse or neglect of a child.

**p. 20**

**0720–14-.04 Administration (10)**

It may be advisable to review Section 10 to determine if state mandated reporting requirements for suspected child abuse should also be incorporated into the commission rules related to required postings at licensed health facilities.

**p.26**

**0720-14-.05 Admissions, Discharges, and Transfers - (24) Infant Abandonment.**

As this appears to contemplate infants not necessarily born in the hospital, this section may need to be revised to incorporate legislative changes that have lengthened the time frames of infant abandonment (beyond 72 hours). These changes are outlined in the state's Safe Haven Law.

**p. 51**

**0720-14-.07 Optional Hospital Services. (13) Perinatal and/or Neonatal Care Services**

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

The Commission may wish to revise this from "June 1997" to its current form, which would read: "the Ninth Edition effective October 14, 2020 and subsequent approved editions."

**p. 53**

**0720-14-.07 Optional Hospital Services. 16. NICU Services**

Clarity may be needed within this section or elsewhere in the document with respect to outlining the process for existing NICUs to continue to operate during this transition to a licensure process.

This could be addressed by adding to 16.a.1. "NICU units operating within a hospital that is in in good standing with the Commission prior to December 1, 2025 are permitted to continue to operate while

their initial licensure application is under review. All existing NICUs must apply for licensure on or before November 30, 2026 when this provision shall no longer be applicable."

**p. 54**

**1. Facility Capacity Requirement (xiii) Facilitate transport**

This currently lists only a Level IV NICU as being required to facilitate transport. We believe that taken with the other suggestions throughout this document related to the Perinatal Regional Center requirements (which are not all necessarily Level IV) that this should be reconsidered to be a requirement of all NICUs (the facilitation of transport) or the definition of facilitation should be further clarified.

**p. 54:**

**2. Education Services – (i) Requirement**

(i) uses the term should vs. the term shall which is defined in the proposed rules (p.11, 104). We believe that "should" ought to be changed to read "shall" or "must" for consistency with the document or be defined for clarity for NICUs seeking to achieve or maintain licensure.

**2. Education Services (iv) Physicians' Education and (v) Site Visits**

There may be some confusion with respect to the role of a Perinatal Regional Center. A center exists within a birthing hospital that provides direct care – therefore the hospital's birthing center and NICU, not the center itself, is the entity which seeks and receives licensure. Section (v) also appears to conflate Regional Perinatal Centers with Level IV NICUs which, as previously outlined, is not correct. The state has at least one Level IV NICU that is not a Perinatal Regional Center and several Perinatal Regional Centers that are located within hospitals with Level III NICUs.

**p. 55:**

**3. Neonatal Care (ii) Neonatal Care Requirement**

The term "Special Care Nursery" is inconsistent with current practice and the aims of this document and should be replaced with the terms Levels II, III, and IV NICUs or NICU, as appropriate.

**3. Neonatal Care (iv) Care of Sick Neonates – essential criteria listing.**

The final item: Provision of appropriate enteral nutrition and lactation support does not have an E in the Level III and IV designation. Please update accordingly for alignment with standards.

**3. Neonatal Care (v) Mechanical Ventilatory Support**

The final item in this section (top of p.56) is inconsistent with the rest of the section and should strike "Level III nurseries" and replace with:

"Unit must be able to provide a full range of respiratory support including sustained conventional and/or high frequency ventilation and inhaled nitric oxide."

And then check E for both Level III and Level IV, as is the consistent practice within this section.

**p. 56:**

**3. Neonatal Care (vii) Laboratory Services**

Clinical laboratory services must be available to fully support clinical neonatal functions.

This currently only lists its requirement for Level IV and Level III NICUs, however this is a requirement of Tennessee's guidelines for Level II NICUs and should be updated according to state guidelines.

**3. Neonatal Care (viii) Transfusion Services**
Transfusion services must be maintained at all times. An appropriately trained technician ***shall*** be available in-house 24 hours a day, 7 days a week.
This currently only lists its requirement for Level IV and Level III NICUs, however this is a requirement of Tennessee's guidelines for Level II NICUs.

Once this is appropriately updated to match the state perinatal guidelines, the final line in this section becomes redundant.

**4. Ancillary Services (i) Laboratory Services**
Clinical laboratory services must be available to fully support clinical neonatal functions.

Level II NICUs must have clinical laboratory services, "E" should be marked here for consistency with state perinatal guidelines.

**p. 57**
**5. Consultation and Transfer (i) Neonatal Transport**
As indicated above (p. 54, b, i) the concept of facilitation of transport needs better definition – all levels of care should facilitate transport and perhaps if this is better defined with respect to incoming (receiving) and outgoing (sending) transport.

To tie back consistently with the prior section (p.54, b, i) and for clarity in this section, each of these section descriptions could read a "NICU unit that operates a receiving transport service" and then the appropriate box should be checked with the corresponding NICU Unit level.
The current construction of this section refers to Level of facility within the text, however the columns checked as essential (E) to the level of NICU do not match with the text.

**5. Consultation and Transfer (iii) Maternal-Fetal and Neonatal Transport**
While the verbiage here appropriately reflects the fact that Regional Perinatal Centers are both Level III and IV, it continues to conflate the requirements of a Regional Perinatal Center (telephone consultation, transport) with all Level IV NICUs. Our Perinatal Centers are both Level III and Level IV NICUs and we have a Level IV NICU which will seek licensure that is not a Perinatal Center.

**p.58**
**6. Maintenance of Data (i) Maintenance of Data and Assessment of Quality Measures**
**(I)** The following items represent the minimum information that should be in medical records maintained at all facilities: (STRIKE ~~at Level II~~ facilities)

**6. Maintenance of Data (i) Maintenance of Data and Assessment of Quality Measures**
**(II)** The text of this section indicates Level II and IV units should (but not using the defined terms shall or must) participate in quality programs, while the columns indicate Level III and IV. We believe that the TAG consensus was a requirement for Level III and IV and a suggestion for participation for Level II.

The key tenant of the law is to create licensure and quality standards. This paragraph, merged with a data collection paragraph, does not appear to provide the necessary clarity surrounding the importance of the quality component, or how it will be evaluated, or at what frequency.

It is our advice that quality be separated from data maintenance and that commitment to quality and how that will be evaluated by the commission be more clearly defined. At minimum:

> *All NICUs shall demonstrate a commitment to evidence-based practice through active participation in a quality initiative each time they are verified or reverified. Level III and Level IV NICUs will submit proof of their active participation by providing documentation from the quality initiative organization at the time of their license verification or re-verification. The Perinatal Advisory Committee will maintain a list of quality initiative programs that will meet the licensure quality requirement.*

We further advise remaining consistent within the document with respect to the state's Perinatal Advisory Committee maintaining the list of quality programs, which may change from time to time. For example the national Children's Hospitals Solutions for Patient Safety and the American Academy of Pediatrics quality programs are not listed here, whereas other programs are listed.

We note that specificity around how participation will be evaluated or at what frequency appears to be missing from the document (alignment with a three-year renewal cycle was discussed by the TAG and would fit with the cadence of quality improvement programs). The Commission may wish to reflect on how the concept of a quality assurance survey is indicated in the hospital licensure, broadly (p.72,13,e) but the concept of a quality assurance survey from the HFC for NICU units is less clearly defined. This appears to be an opportunity for improvement to meet the goals of the legislature that this process for licensure include meaningful quality measures.

**6. Maintenance of Data (ii) Data Collection**
As previously highlighted, the Regional Perinatal Centers are not necessarily a Level IV NICU and they sit within a birthing hospital which would distinctly carry a level of care designation (typically Level III or IV). There is a Level IV NICU which is not a Regional Perinatal Center. It is unclear why the Perinatal Regional Center (distinct from a NICU unit) is listed as if it (the center, not the NICU) is subject to licensure separate from the licensure of the unit.

**p. 59**
**7. Personnel Qualifications and Functions (i) I, Director**
"In a Level II hospital" we believe is meant to be read as a "Level II unit"

**7. Personnel Qualifications and Functions (i) II Neonatologists**
As written, it appears that several of the requirements listed as required for Level II NICUs ought to also be included in requirements of Level III and IV. (see above, p. 8, 66 for similar issue of consistency).

It is important in the final version of this section as adopted to recall that we have a Level IV NICU that is not a birthing center – and that these requirements are specific to NICUs and not to the birthing hospital. Therefore some additional thought may be given related to the wording and requirements related to obstetrics in this section.

**7. Personnel Qualifications and Functions (i) V Deliveries**
The requirement related to deliveries of high-risk fetuses exists for every level of NICU. As currently structured the document has separated II and III and IV but the information is the same.

It is also important that the rules reflect that we have several existing NICUs which will seek licensure that are not birthing centers (East Tennessee Children's Hospital, Le Bonheur Children's Hospital, St.

Jude Children's Research Hospital) and the licensure rules should reflect this separation in duties of licensure for birthing facilities from NICU units within a hospital that may not deliver babies.

**7. Personnel Qualifications and Functions (i) VIII Sub-specialty Consultants**
For consistency with this section and others (example: type of physician should be XYZ vs. “Should have”) we ask that the staff clarify this section and clarify “on call” and “readily available” -as consistent with other sections where specific definitions (within 30 minutes of the hospital, 24/7, etc) are provided.

**p. 61**
**7. Personnel Qualifications and Functions (ii) I The Nurse Manager**
This section continues to use the term nursery vs. NICU and should be updated to be consistent with state and national guidelines. Within this section the Level II verbiage is inconsistent with the pattern established in the writing of the level IV and III and the commission staff may wish to address this.

**p. 62**
**7. Personnel Qualifications and Functions (iv) I Case Manager / Discharge Coordinator**
Bereavement support is required by case management at all levels. These two sections can be combined into one with the same requirement for Levels II, III, and IV.

**7. Personnel Qualifications and Functions (iv) II Post-discharge Maternal Follow-up**
We recommend that this section be struck. It is important that the rules reflect an awareness that these licensure and quality standards are for NICUs and that Tennessee have several existing NICUs which will seek licensure that are not birthing centers (East Tennessee Children’s Hospital, Le Bonheur Children’s Hospital, St. Jude Children's Research Hospital).

**7. Personnel Qualifications and Functions (iv) III Post-discharge Neonatal Follow-up**
Regional Perinatal Centers are located at both Level III and Level IV NICUs. It is not clear if this is intended to apply to centers, or to NICUs. It is likely that this is intended for both Level III and Level IV NICUs, irrespective of their status as a Regional Perinatal Center.

**7. Personnel Qualifications and Functions (iv) V Respiratory Therapists**
This section continues to use the term nursery vs. NICU and should be updated to NICU to be consistent with state and national guidelines.

**7. Personnel Qualifications and Functions (iv) VII Pharmacist**
There is no distinction between the two descriptions. These should be combined into a requirement for all Level II, III, and IV NICUs.

**p. 63**
**8. Space and Equipment for l~~evel II facilities~~ NICU Units**
Correct the header to remove Level II. The unit type delineation is provided in the columns below, not the section header.

**8. Space and Equipment for NICU Units (i) Physical facilities and equipment**
This section continues to use the term nursery vs. NICU and should be updated to NICU to be consistent with state and national guidelines.

**8. Space and Equipment for NICU Units (ii) Minimal Equipment for the normal infant includes**

The categorical headers II and III may be collapsed and a single header amended to better encompass the listing:
“Equipment necessary for NICU Units”

**p. 64**

**(c) 1. The NICU must have a NICU Director who is responsible for the following:**
It is unclear what state or national guidelines this is referencing. Within the guidelines, p.59, Section 7.Personnel Qualifications and Functions (i) I – Director – references the requirements of the Director and responsibilities. As indicated above in the notes related to this section, you may wish to revise this for clarity and then to delete this additional reference created on p. 64 without clear tie-in to state standards.

**(c) 1. (iv) Any other requirements in 0720-48-.02.**
We are not able to locate this reference in the HFC rules. Per the Tennessee Secretary of State Rules, the Health Facilities Commission Rules end 0720-46.
This references a rule 0720-48-02 which is not listed on the Secretary of State’s listing for Section 720, here: https://publications.tnsosfiles.com/rules/0720/0720.htm

**(d) A NICU patient qualifying for lvl III care may be able to receive lvl II care services and continue as a patient if the patient’s treating physician certifies that such care can be appropriately provided in the lvl II NICU.**
The above statement is inconsistent with state and national guidelines in terminology and practice (and with the remainder of the drafted rules). This should be removed due to the confusion it will cause in the purpose of promulgating standards for quality and licensure related to NICU units. The purpose of this process is to define for purposes of licensure the qualifications required to reach a level II, III, or IV NICU designation from the State Health Facilities Commission. This section is not consistent with that purpose.

**From:** Lattimore, Keri A
**To:** Scott Faragher
**Subject:** [EXTERNAL] Comments on NICU Licensure proposal
**Date:** Friday, June 13, 2025 3:43:06 PM



Under levels of care-Neonatal Intensive Care units II-IV requirements:
2. Education

All neonatal care providers should maintain NRP, but S.T.A.B.L.E should not be required for all levels of care. The concepts of STABLE are practiced daily in Level III and IV NICUs. I believe it's most useful for Level I nurseries and Level II NICUs. I know this is taken directly from current Tennessee Perinatal Guidelines.

This year, the guidelines will be updated. Remind me how easy the process is to change these rules when the guidelines change?

2 Educational services
Iv: E should also be marked under level III for "For the Staff of the Regional Perinatal Center: A program of professional education must be maintained for the staff of the Regional Perinatal Center. These programs should satisfy the educational requirements for physicians, nurses, social workers, and others who function in the administration of Level III or Level IV care'
There are some level III NICUs that are regional perinatal centers (UT Medical center, Knoxville).

Same for "For the Staff of Other Hospitals in the Region: The Regional Perinatal Center must maintain a program of professional outreach education for hospitals within its region. These programs of instruction require a staff of qualified educators to present ongoing courses to Level I, II, and III hospitals. These courses must satisfy the educational objectives set forth in the series of publications for the education of nurses and social workers published by the Tennessee Department of Health." Also place an E under Level III column.

And same for "The Regional Perinatal Center staff will engage in site visits upon request within its region." Place an E in the III column.

3. Neonatal Care
Resuscitation: All levels should be able to "Provision must be made for resuscitation of infants immediately after birth. Resuscitation capabilities should include assisted ventilation with blended oxygen administered by bag or T-piece resuscitator with mask or endotracheal tube, chest compression, and appropriate intravascular therapy. Refer to the most recent

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All levels should be able to "Transport to a special care nursery requires a capacity for uninterrupted support. An appropriately equipped pre-warmed transport incubator, with blended oxygen, should be used for this purpose."

All levels should be able to : Recurrent observation of the neonate should be performed by personnel who can identify and respond to the early manifestations of neonatal disorders.

(iv) Care of sick neonates.
All levels should be able to provide the care under (l)

(v) Mechanical Ventilatory support
All levels should be able to provide care listed under (l) EXCEPT: "Level III nurseries should be able to provide a full range of respiratory support, including sustained conventional and/or high frequency ventilation and inhaled nitric oxide" should continue to be limited to Level IV and III
Rationale: We are allowing Level II NICUs to provide limited mechanical ventilation for 24 hours.

5. Consultation and transfer
(ii): add an E under level III for all rows since it reference regional perinatal centers.

Maintenance of data (II) "A systematic ongoing compilation of data should be maintained to reflect the care of sick patients, in addition to the listing of minimal data that is specified for Level I, Level II, and Level III facilities. All Level II, III, & IV programs should participate in a state or national continuous quality improvement initiative that includes ongoing data collection and review for benchmarking and evaluation of outcomes. Examples of continuous quality improvement initiatives available in Tennessee are those provided by TIPQC and THA."
Also add a E under level II

Data Collection The Regional Perinatal Center must compile data (Program Objectives Report [POR]) on educational outreach that is performed as well as the region's..... Add an E under level III since reference perinatal center.

Post-discharge Maternal Follow-up Follow-up evaluation of selected women who are discharged from the Regional Perinatal Center should be arranged. Does this need to be included in NICU licensing??? It specifically is for maternal follow up care.

Post-discharge Neonatal Follow-up Follow-up evaluation of selected infants who are discharged from the Regional Perinatal Center should be performed. Neonatal intensive care

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Post-discharge Neonatal Follow-up Follow-up evaluation of selected infants who are discharged from the Regional Perinatal Center should be performed. Neonatal intensive care

unit graduates who are considered high risk and those with birthweights <1500 grams should be enrolled in an organized follow-up program that tracks and records medical and neurodevelopmental outcomes to allow later analysis. Add an E under level III

Thanks
Keri

*Keri A. Lattimore, MD*

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VANDERBILT UNIVERSITY
MEDICAL CENTER

*Matthew Scanlan, JD*
*Vice President, Office of State/Local Government and Community Affairs*

May 6, 2025

Tennessee Health Facilities Commission
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Dear Member of the Health Facilities Commission:

We are writing to express concerns with the omission of certain licensure standards in the rulemaking proposed for Neonatal Intensive Care Units ("NICUs").

During the debate on the removal of NICU from the CON process and move toward a licensure model, sponsors of this legislation spent a considerable amount of time discussing how that model would enable the Commission to implement quality standards as part of its licensing process. The legislative intent was accurately posted on the Health Facilities Commission website which reads:

> "Effective December 1, 2025, Public Chapter 985 removes the Certificate of Need (CON) requirements for Neonatal Intensive Care Units (NICU), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), and Burn Units and transitions those project types into *the licensure program with quality requirements*. HFC solicited experts on a voluntary basis in the field of imaging, neonatal intensive care, and burn care to create Technical Advisory Group (TAG) recommendations for guidance in the *development and incorporation of quality regulations into the licensure process*."
> [Emphasis added]

VUMC has been very involved with the development of the TAG recommendations to implement the sponsor's extent that the Health Facilities Commission create meaningful quality standards for NICU, MRI, PET, and Burn Units.

The recommendations of the NICU TAG contained significant and important quality recommendations that have been omitted from this rulemaking proposal. We urge the Commission to emphasize to staff the importance of these recommendations and require that they be included in the final rulemaking. VUMC has some concerns regarding the currently drafted rules regarding NICU.

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Nashville, TN 37212

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**NICU Participation in a Quality Collaborative**

The TAG made a strong recommendation, with no objections from TAG members, that NICU re-licensure should be tied to meaningful participation in what is known as a "Quality Collaborative" designed to help hospitals implements evidence-based best NICU practices. This recommendation – which again had full TAG membership support - has been removed from the rule as currently drafted. The staff gave a number of reasons to the TAG members for removing the recommendation. The staff reasons and VUMC's responses to them are below.

1. Duplication of what already existed in Hospital licensure.

   *VUMC Response: Although Quality Improvement (QI) requirements may exist for hospital licensure, we are not aware of any requirement that includes meaningful QI implementing best practices with regard to NICUs or newborns. The fact that no hospital currently is required to do meaningful QI work at the level of the NICU is exactly what the TAG found important to impact with these rule changes.*

2. Opportunities exist for agencies like The Joint Commission to implement appropriate QI outside of the licensure process.

   *VUMC Response: Again, the QI work prompted by The Joint Commission does not necessarily include NICUs or newborns and tends to focus on analysis of sentinel events. In contrast, participation in a quality collabortative takes a more global approach to implementing best practices for a population of newborn infants.*

3. Engagement in a quality collaborative would be a cost to a hospital and would not be appropriate for a rule:

   *VUMC Response: Although some quality collaboratives (e.g. Vermont Oxford Network, Children's Hospital Neonatal Consortium) have a cost associated with membership,* ***participation in the Tennessee Initiative for Perinatal Quality Care (TIPQC) is at no cost*** *to hospitals in the state. Moreover, TIPQC, which is in part funded by the Tennessee Department of Health, develops the toolkits, implementation strategies, and provides other support to hospitals as they put in place best practices.*

4. Site-visitors during licensure and level of care verification could not possibly survey this accurately:

   *VUMC Response: All of the quality collaboratives suggested above, including TIPQC, are able to provide documentation of participation in their program. Although we would hope participation would improve outcomes for newborns, it would not be necessary to demonstrate improvements to site-visitors - only participation in a quality collaborative.*

In conclusion, VUMC believes (along the other members of the NICU TAG) that it is very important to include NICU participation in a quality collaborative in the revised rules. Thank you for your consideration of this important matter.

Sincerely,

Matthew Scanlan, Esq., Vice President
Office of State Government and Community Affairs
Vanderbilt University Medical Center
Email: matthew.j.scanlan@vumc.org

Page 51 (revised version):

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

- Would recommend this be the current or the most recent edition of the Guidelines, not the June,1997 version (has been updated several times since 1997)

3. Neonatal Care

Page 55-57 (revised version):

Provision must be made for resuscitation of infants immediately after birth. Resuscitation capabilities should include assisted ventilation with blended oxygen administered by bag or T-piece resuscitator with mask or endotracheal tube, chest compression, and appropriate intravascular therapy. Refer to the most recent edition of the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program Guidelines for a complete list of resuscitation equipment and supplies.

- Not included as essential for Level II NICU but should be.

**Transport from Delivery Room to the Special Care Nursery**
Transport to a special care nursery requires a capacity for uninterrupted support. An appropriately equipped pre-warmed transport incubator, with blended oxygen, should be used for this purpose.

- Special Care Nursery is a poorly defined term, should be NICU; should also be essential for Level II NICUs.

**Transitional Care**
Recurrent observation of the neonate should be performed by personnel who can identify and respond to the early manifestations of neonatal disorders.

- Should also be essential for Level II NICUs.

**Care of Sick Neonates**

The care of moderately and severely ill infants entails the following essentials:

Continuous cardiorespiratory monitoring.
Serial blood gas determinations and non-invasive blood gas monitoring.

Periodic blood pressure determinations (intra-arterial when necessary).

Portable diagnostic imaging for bedside interpretation.

~~Availability of electrocardiograms and echocardiograms with rapid interpretation.~~

Laboratory Services: Clinical laboratory services must be available to fully support clinical neonatal functions.

Fluid and electrolyte management and administration of blood and blood components.

Phototherapy and ~~exchange transfusion.~~

~~Administration of parenteral nutrition through peripheral or central vessels.~~

Provision of appropriate enteral nutrition and lactation support.

- Should also be essential for Level II (except for where crossed out).

**Mechanical Ventilatory Support**
(I) Unit must be qualified to provide mechanical ventilatory support. The essential qualifications are as follows:
Continuous in-house presence of personnel experienced in airway management, endotracheal intubation, and diagnosis and treatment of air leak syndromes.
A staff of nurses (R.N.) and respiratory therapists (R.T.) who are specifically educated in the management of neonatal respiratory disorders.
Blood gas determinations and other data essential to treatment must be available 24 hours a day, 7 days a week.

- Should also include Level II NICUs as they can use mechanical ventilation for up to 24 hours.

**Neonatal Transport:**

The Level IV facility that operates a transport service is required to maintain equipment and a trained team of personnel for the transport of newborn patients. The team and equipment must be available at all times. The Level IV facility is responsible for transport of referred infants with its own equipment, or alternatively, with equipment from a commercial source.

The Level IV facility that operates a transport service should originate a protocol that describes procedures, staffing patterns, and equipment for the transport of referred infants. The protocol should conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health.

The Level IV facility that operates a transport service is required to maintain EE records of its activities. (See the most recent edition of the Tennessee
Perinatal Care System Guidelines for Transportation.)

- Above wording in guidelines refers only to level IV but listed as E (essential) for both level III and IV NICUs. Should change Level IV facility to either Level III and Level IV facility or just facility.

Page 58 (revised):

A systematic ongoing compilation of data should be maintained to reflect the care of sick patients, in addition to the listing of minimal data that is specified for Level I, Level II, and Level III facilities. All Level II & IV programs should participate in a state or national continuous quality improvement initiative that includes ongoing data collection and review for benchmarking and evaluation of outcomes. Examples of continuous quality improvement initiatives available in Tennessee are those provided by TIPQC and THA.

- This says level II and IV programs should participate in QI initiative; chart indicates essential (E) for level III and IV; should be level II, III, and IV in both places.

Page 63 (revised):

(d) A NICU patient qualifying for lvl III care may be able to receive lvl II care services and continue as a patient if the patient's treating physician certifies that such care can be appropriately provided in the lvl II NICU.

- This is not in agreement with state perinatal guidelines and seems problematic. This is a slippery slope and would allow for critically ill infants to be cared for in facilities not equipped to care for them based on the "judgement" of a provider. Lots of room for bias and conflict of interest here and potential poor outcomes for infants who deteriorate unexpectedly.

Not included in the Rules but recommended as a requirement for licensure as a Level II, III, or IV NICU by the NICU TAG without objection from the TAG members. Request that this be added to the Rules:

NICUs must demonstrate continuous participation in an annual quality improvement initiative for implementation of evidenced-based best practices involving the care of newborns. Examples of programs include, but are not limited to:

- Tennessee Initiative for Perinatal Quality Care (TIPQC)
- Vermont Oxford Network (VON)
- Children's Hospitals' Neonatal Consortium (CHNC)

The staff gave a number of reasons to the TAG members for removing the recommendation. The staff reasons and VUMC's responses to them are below.

1. Duplication of what already existed in Hospital licensure.

   *VUMC Response: Although Quality Improvement (QI) requirements may exist for hospital licensure, we are not aware of any requirement that includes meaningful QI implementing best practices with regard to NICUs or newborns. The fact that no hospital currently is required to do meaningful QI work at the level of the NICU is exactly what the TAG found important to impact with these rule changes.*

2. Opportunities exist for agencies like The Joint Commission to implement appropriate QI outside of the licensure process.

   *VUMC Response: Again, the QI work prompted by The Joint Commission does not necessarily include NICUs or newborns and tends to focus on analysis of sentinel events. In contrast, participation in a quality collaborative takes a more global approach to implementing best practices for a population of newborn infants.*

3. Engagement in a quality collaborative would be a cost to a hospital and would not be appropriate for a rule:

   *VUMC Response: Although some quality collaboratives (e.g. Vermont Oxford Network, Children's Hospital Neonatal Consortium) have a cost associated with membership,* ***participation in the Tennessee Initiative for Perinatal Quality Care (TIPQC) is at no cost to hospitals in the state****. Moreover, TIPQC, which is in part funded by the Tennessee Department of Health, develops the toolkits, implementation strategies, and provides other support to hospitals as they put in place best practices.*

4. Site-visitors during licensure and level of care verification could not possibly survey this accurately:

*VUMC Response: All of the quality collaboratives suggested above, including TIPQC, are able to provide documentation of participation in their program. Although we would hope participation would improve outcomes for newborns, it would not be necessary to demonstrate improvements to site-visitors - only participation in a quality collaborative.*

Optional Hospital Services

Page 52:

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

- Would recommend this be the current or the most recent edition of the Guidelines, not the June,1997 version (has been updated several times since 1997). The Guidelines are updated on a 5-year cycle.

3. Neonatal Care

Page 56:

Provision must be made for resuscitation of infants immediately after birth. Resuscitation capabilities should include assisted ventilation with blended oxygen administered by bag or T-piece resuscitator with mask or endotracheal tube, chest compression, and appropriate intravascular therapy. Refer to the most recent edition of the American Heart Association and American Academy of Pediatrics Neonatal Resuscitation Program Guidelines for a complete list of resuscitation equipment and supplies.

- Not included as essential (E) for Level II NICU but should be. The birth of a critically ill infant at a level II NICU is not uncommon. These infants may require significant resuscitation and stabilization prior to transfer to a higher-level NICU.

**Transport from Delivery Room to the Special Care Nursery**
Transport to a special care nursery requires a capacity for uninterrupted support. An appropriately equipped pre-warmed transport incubator, with blended oxygen, should be used for this purpose.

- Special Care Nursery is a poorly defined term, should be replaced with NICU; should also be essential (E) for Level II NICUs.

**Transitional Care**
Recurrent observation of the neonate should be performed by personnel who can identify and respond to the early manifestations of neonatal disorders.

- Should also be essential (E) for Level II NICUs.

**Care of Sick Neonates**

The care of moderately and severely ill infants entails the following essentials:

Continuous cardiorespiratory monitoring.
Serial blood gas determinations and non-invasive blood gas monitoring.

Periodic blood pressure determinations (intra-arterial when necessary).

Portable diagnostic imaging for bedside interpretation.

~~Availability of electrocardiograms and echocardiograms with rapid interpretation.~~
Laboratory Services: Clinical laboratory services must be available to fully support clinical neonatal functions.

Fluid and electrolyte management and administration of blood and blood components.
Phototherapy and ~~exchange transfusion.~~
~~Administration of parenteral nutrition through peripheral or central vessels.~~

Provision of appropriate enteral nutrition and lactation support.

- Should also be essential (E) for Level II NICUs (except for where crossed out).

**Mechanical Ventilatory Support**
(I) Unit must be qualified to provide mechanical ventilatory support. The essential qualifications are as follows:
Continuous in-house presence of personnel experienced in airway management, endotracheal intubation, and diagnosis and treatment of air leak syndromes.
A staff of nurses (R.N.) and respiratory therapists (R.T.) who are specifically educated in the management of neonatal respiratory disorders.
Blood gas determinations and other data essential to treatment must be available 24 hours a day, 7 days a week.

- Should also be essential (E) for Level II NICUs as they can use mechanical ventilation for up to 24 hours. This would also ensure that Level II NICUs have appropriately trained staff for non-invasive modes of respiratory support that they commonly use, such as CPAP, bubble CPAP, and high flow nasal cannula.

Page 58:

**Neonatal Transport:**

The Level IV facility that operates a transport service is required to maintain equipment and a trained team of personnel for the transport of newborn patients. The team and equipment must be available at all times. The Level IV facility is responsible for transport of referred infants with its own equipment, or alternatively, with equipment from a commercial source.

The Level IV facility that operates a transport service should originate a protocol that describes procedures, staffing patterns, and equipment for the transport of referred infants. The protocol should

conform to the most recent edition of the Tennessee Perinatal Care System Guidelines for Transportation, published by the Tennessee Department of Health.

The Level IV facility that operates a transport service is required to maintain EE records of its activities. (See the most recent edition of the Tennessee
Perinatal Care System Guidelines for Transportation.)

- Above wording in guidelines refers only to level IV but listed as essential (E) for both level III and IV NICUs in Table. Should change Level IV facility to either "Level III and Level IV facility" or just "facility".

Page 64:

(d) A NICU patient qualifying for lvl III care may be able to receive lvl II care services and continue as a patient if the patient's treating physician certifies that such care can be appropriately provided in the lvl II NICU.

- This is not in agreement with state perinatal guidelines and seems problematic. This is a slippery slope and would allow for critically ill infants to be cared for in facilities not equipped to care for them based on the "judgement" of a provider. Lots of room for bias and conflict of interest here and potential poor outcomes for infants who deteriorate unexpectedly. This is why we have Perinatal Regional Centers with transport teams to manage the transport of critically ill neonates.