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Sequence Number: 08-10-23
Rule ID(s): 9913
File Date: 8/11/2023
Effective Date: 11/9/2023

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205)

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission: TN Health Facilities Commission, Board for Licensing Health Care Facilities
Division: N/A
Contact Person: Logan Grant, Executive Director
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Revision Type (check all that apply):

☒ Amendment
☐ New
☐ Repeal
☒ Content based on previous emergency rule filed on 12/27/2022
☒ Content is identical to the emergency rule

Rule(s) (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that ALL new rule and repealed rule numbers are listed in the chart below. Please enter only ONE Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0720-14	Standards for Hospitals
Rule Number	Rule Title
0720-14-.01	Definitions
0720-14-.06	Basic Hospital Functions

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to <https://sos.tn.gov/products/division-publications/rulemaking-guidelines>.

Chapter Number 0720-14
Standards for Hospitals

Rule 0720-14-.01 Definitions is amended by deleting paragraph (23) in its entirety and substituting instead the following language, and is further amended by adding new paragraphs (82) and (83), and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraphs shall read:

- (23) **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.
- (82) **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.

- (83) 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.

Authority: 42 U.S.C. 1395x(kkk); 42 U.S.C. §1395cc(j); T.C.A. §§ 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, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.

Rule 0720-14-.06 is amended by adding new paragraph (11), so that as amended, the new paragraph shall read:

(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
 - 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).
 - 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: 42 U.S.C. 1395x(kkk); 42 U.S.C. §1395cc(j); T.C.A. §§ 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, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Paul C. Boyd	X				
Louis F. Caputo	X				
Howard Daniel Clark, D.D.S.				X	
Patsy E. Crichfield				X	
Joshua A. Crisp				X	
James Dunn, Executive Director Commission on Aging and Disability	X				
Julie Jeter, M.D.	X				
Patricia P. Kettermann				X	
Tom Marshall	X				
Bobby G. Meadows	X				
Roger L. Mynatt	X				
Jennifer Tatum- Cranford, Pharm.D.				X	
Gina Throneberry	X				
Monica Warhaftig, D.O.	X				
Christopher Wilson, M.D., Chairman	X				
VACANT					
VACANT					
VACANT					
VACANT					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Health Facilities Commission, Board for Licensing Health Care Facilities on 06/06/2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 03/21/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 06/06/2023

Date: 7/12/2023

Signature: 

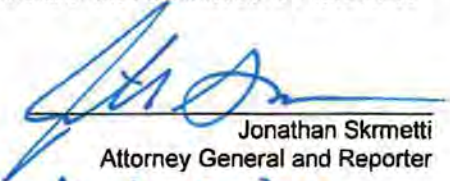
Name of Officer: Logan Grant

Title of Officer: Executive Director

Agency/Board/Commission: TN Health Facilities Commission, Board for Licensing Health Care Facilities

Rule Chapter Number(s): 0720-14

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.


Jonathan Skrmetti
Attorney General and Reporter
August 10, 2023
Date

Department of State Use Only

Filed with the Department of State on: 8/11/2023

Effective on: 11/9/2023


Tre Hargett
Secretary of State

RECEIVED

Aug 11 2023, 12:00 pm

Secretary of State
Division of Publications

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

No public comments were made during the rulemaking hearing.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

(Insert statement here)

The proposed rule amendments are not expected to have an impact on small business.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

(Insert statement here)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rule amendments expand the definition of designation to include Rural Emergency Hospitals, as well as define Rural Emergency Hospital and Rural Emergency Hospital Services. The requirements for designation as a Rural Emergency Hospital have also been added.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Rural Emergency Hospitals (REHs) are a new provider type established by the federal Consolidated Appropriations Act, 2021 to address the growing concern over closures of rural hospitals. The REH designation provides an opportunity for Critical Access Hospitals (CAHs) and certain rural hospitals to avert potential closure and continue to provide essential services for the communities they serve. Conversion to an REH allows for the provision of emergency services, observation care, and additional medical and health outpatient services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. This new provider type, effective January 1, 2023, will promote equity in health care for those living in rural communities by facilitating access to needed services. The final federal rules concerning Rural Emergency Hospitals were not published until November 2022, and have an effective date of January 1, 2023.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Tennessee Hospital Association and Tennessee Health Care Association are in support of this rule.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

N/A

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

There will be minimal fiscal impact on state and local government.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Logan Grant, Executive Director.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Logan Grant, Executive Director.

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

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(l) Any additional information relevant to the rule proposed for continuation that the committee requests.

N/A

**RULES
OF
THE TENNESSEE HEALTH FACILITIES COMMISSION**

**CHAPTER 0720-14
STANDARDS FOR HOSPITALS**

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0720-14-.01 DEFINITIONS.

- (1) Abuse. The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.
- (2) Acceptable Plan of Correction. The Licensing Division 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.
- (3) Adult. An individual who has capacity and is at least 18 years of age.
- (4) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.
- (5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.
- (6) Board. The Tennessee Board for Licensing Health Care Facilities.
- (7) 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) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions,

(Rule 0720-14-.01, continued)

- 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) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.
 - (10) 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) 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) Certified Respiratory Therapist. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.
 - (13) Certified Respiratory Therapy Technician. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.
 - (14) 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) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professional, e.g., licensed physicians and mid-level practitioners.
 - (16) Collaborative Plan. The formal written plan between the mid-level practitioners and a licensed physician.
 - (17) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.
 - (18) Competent. A patient who has capacity.
 - (19) 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.
 - (20) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.
 - (21) Department. The Tennessee Department of Health.
 - (22) 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.

(Rule 0720-14-.01, continued)

- (23) ~~Designation. An official finding and recognition by the Department of Health that an acute care hospital meets Tennessee State Rural Health Care Plan requirements to be a Critical Access Hospital.~~

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.

- (24) 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.
- (25) 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.
- (26) 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.
- (27) 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.
- (28) 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.
- (29) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetists' Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.
- (30) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.
- (31) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.
- (32) 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).
- (33) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.
- (34) 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.

(Rule 0720-14-.01, continued)

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

(36) 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.

(37) 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 nonrelated 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.

(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

(Rule 0720-14-.01, continued)

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.
- (38) 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.
 - (39) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.
 - (40) Individual instruction. An individual's direction concerning a health care decision for the individual.
 - (41) 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.
 - (42) 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.
 - (43) 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.
 - (44) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(Rule 0720-14-.01, continued)

- (45) 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.
- (46) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (47) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.
- (48) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (49) 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.
- (50) 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.
- (51) 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.
- (52) 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.
- (53) Member of the Professional Medical Community. A professional employed by the hospital and on the premises at the time of a voluntary delivery.
- (54) Mid-Level Practitioner. Either a certified nurse practitioner or a physician assistant.
- (55) 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.
- (56) 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.

(Rule 0720-14-.01, continued)

- (57) N.F.P.A. The National Fire Protection Association.
- (58) Nuclear Medicine Technologist. A person currently registered as such by the National Association for Nuclear Medicine Technology.
- (59) 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.
- (60) Occupational Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (61) Occupational Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (62) Optometrist. A person currently licensed as such by the Tennessee Board of Optometry.
- (63) 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.
- (64) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
- (65) Personally Informing. A communication by any effective means from the patient directly to a health care provider.
- (66) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.
- (67) Physical Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (68) Physical Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (69) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.
- (70) 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.
- (71) Physician Orders for Scope of Treatment or POST. Written orders that:
 - (a) Are on a form approved by the Board for Licensing Health Care Facilities;
 - (b) Apply regardless of the treatment setting and that are signed as required herein by the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist; and
 - (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

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3. Specify both 1 and 2.

- (72) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.
- (73) 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.
- (74) Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.
- (75) 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.
- (76) Radiological Technologist. A person currently registered as such by the American Society of Radiological Technologists.
- (77) 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.
- (78) Registered Health Information Administrator (RHIA). A person currently registered as such by the American Health Information Management Association.
- (79) Registered Health Information Technician (RHIT). A person currently accredited as such by the American Health Information Management Association.
- (80) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (81) 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.

(82) 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.

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- (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.
- (83) 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.
- ~~(82)~~(84) Satellite Hospital. A freestanding hospital licensed with a parent hospital that is on separate premises and operated under the same management.
- ~~(83)~~(85) Shall or Must. Compliance is mandatory.
- ~~(84)~~(86) 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)~~(87) 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)~~(88) 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)~~(89) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board.
- ~~(88)~~(90) 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.

(Rule 0720-14-.06, continued)

~~(89)~~(91) 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)~~(92) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

~~(91)~~(93) 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)~~(94) 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)~~(95) 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)~~(96) 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, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.~~

~~Authority: 42 U.S.C. §1395x(kkk); 42 U.S.C. §1395cc(i); T.C.A. §§ 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, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.~~

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.

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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.

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.

(Rule 0720-14-.06, continued)

- (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

(Rule 0720-14-.06, continued)

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

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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; and
 8. 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 hospitalwide 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

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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.
- (g) All hospitals shall each year from October 1 through March 1 offer 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

(Rule 0720-14-.06, continued)

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

(Rule 0720-14-.06, continued)

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

(Rule 0720-14-.06, continued)

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:

(Rule 0720-14-.06, continued)

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.
 - (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

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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.

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- (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.

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- (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

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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.
 - (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

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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;

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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
 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).
 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, 68-3-511, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216. Authority: 42 U.S.C. §1395x(kkk); 42 U.S.C. §1395cc(l); T.C.A. §§ 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, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.~~ **Administrative History:** Original rule filed March 18, 2000; effective May 30, 2000.

(Rule 0720-14-.06, continued)

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