NEW

ALABAMA STATE BOARD OF HEALTH ALABAMA DEPARTMENT OF PUBLIC HEALTH ADMINISTRATIVE CODE CHAPTER 420-5-23 RURAL EMERGENCY HOSPITALS

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420-5-23-.01 General Provisions.

(1) Legal Authority for Adoption of Rules. The following rules for Rural Emergency Hospitals are adopted by the Alabama State Board of Health pursuant to §22-21-20, et seq., <u>Code of Ala. 1975</u>.

(2) Definitions.

(a) "Administrator" means a natural person who is the governing authority of the rural emergency hospital (REH) or a natural person who is designated by the governing authority of the REH and who is delegated the responsibility and authority for the interpretation, implementation, and proper application of policies and programs established by the governing authority. The administrator is delegated responsibility for the establishment of safe and effective administrative management, control, and operation of the services provided.

(b) "Anesthesiologist" means a person currently licensed by the Medical Licensure Commission of Alabama to practice medicine in Alabama pursuant to the provisions contained in current state statutes.

(c) "Anesthesiologist Assistant" means a person currently licensed by the Alabama State Board of Medical Examiners to perform anesthesiology services in Alabama under the direct supervision of an Alabama licensed anesthesiologist pursuant to the provisions contained in current state statutes.

(d) "Board" or "State Board of Health" means the Alabama State Board of Health.

(c) "Certified Registered Nurse Anesthetist" (CRNA) means a registered nurse who is certified to provide advanced practice nursing as a nurse anesthetist and is presently licensed to practice nursing by the Alabama Board of Nursing under the provisions contained in current state statutes.

(f) "Clinical Nurse Specialist" means a registered nurse who, through study and supervised practice at the graduate level and as evidenced by certification, has advanced knowledge and practice skills in a specialized area of practice, and is presently licensed to practice nursing by the Alabama Board of Nursing under the provisions contained in current state statutes.

(g) "Critical Access Hospital" (CAH) means a hospital licensed by the Department that provides inpatient care for an average annual length of stay not to exceed 96 hours, complies with Alabama's Rural Health Plan and all requirements applicable to general hospitals, and has a maximum of 45 beds.

(h) "Dentist" or doctor of dental surgery or dental medicine means a person currently licensed by the Board of Dental Examiners of Alabama to practice dentistry in Alabama pursuant to the provisions contained in current state statutes.

(i) "Department" means the Alabama Department of Public Health.

(j) "Governing Authority" means the owner(s), hospital association, county hospital board, board of directors, board of governors, board of trustees, or any other comparable designation of a body duly organized and constituted for the purpose of owning, acquiring, constructing, equipping, operating, and maintaining an REH, and exercising control over the affairs of said hospital.

(k) "Hospital" means a health institution licensed in Alabama by the Board which is planned, organized, and maintained pursuant to the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

(1) "License" means the legal authority to operate an REH and to offer and provide care as permitted under these rules. A license may only be granted by the Board through the actions of its authorized agents.

(m) "License Certificate" means a document issued by the Department showing that the entity named on the document is licensed as an REH. A license certificate shall contain the signature of the State Health Officer and other seals and markings designed to demonstrate its authenticity. The license certificate shall be posted in a conspicuous place on the hospital premises.

(n) "Licensed Practical Nurse" (LPN) means a person currently licensed by the Alabama Board of Nursing to assist physicians and registered nurses and to provide such services in Alabama under the provisions contained in current state statutes.

(o) "Medical Director" means a physician currently licensed by the Medical Licensure Commission of Alabama to practice medicine and/or surgery and is responsible for planning, organizing, conducting, and directing the medical affairs of the REH.

(p) "Nurse Practitioner" (NP) means a certified registered nurse practitioner (CRNP) who is certified to provide advanced practice nursing in the delivery of nursing services within a health care system that provides for consultation, collaborative management, or referral as indicated by the health status of the client and is presently licensed to practice nursing by the Alabama Board of Nursing under the provisions contained in current state statutes. CRNPs practice pursuant to a collaborative agreement with a physician licensed by the Medical Licensure Commission of Alabama.

(q) "Physician" means a person currently licensed by the Medical Licensure Commission of Alabama to practice medicine in Alabama under the provisions contained in current state statutes. The term includes both doctors of medicine and doctors of osteopathy.

(r) "Physician Assistant" (PA) means a person currently licensed by the Alabama State Board of Medical Examiners to perform medical services in Alabama under the supervision of a licensed physician pursuant to the provisions contained in current state statutes. (s) "Podiatrist" or doctor of podiatric medicine means a person currently licensed by the State of Alabama Board of Podiatry to practice podiatry in Alabama pursuant to the provisions contained in current state statutes.

(t) "Principal" means an individual associate with a governing authority or a license applicant in any of the following capacities:

- 1. Administrator, or equivalent;
- 2. Chief Executive Officer, or equivalent;

3. Owner of a controlling interest in the governing authority, or, if the governing authority is a subsidiary of another business entity, owner of a controlling interest in the parent business entity; or

4. If no person has a controlling interest in the governing authority or in a parent corporation of the governing authority, then an owner of 10 percent or more of the governing authority or of any business entity of which the governing authority is a subsidiary.

(u) "Registered Nurse" (RN) means a person who provides nursing services and holds an active license issued by the Alabama Board of Nursing.

(v) "Rural Emergency Hospital" (REH) means a licensed hospital that, as of December 27, 2020, was previously licensed by the Board as a critical access hospital or a general acute care hospital, as defined in Section 1886(d)(1)(B) of the Social Security Act, with no more than 50 beds, that is considered rural, as defined in Section 1886(d)(2)(D)of the Social Security Act; or that, as of December 27, 2020, was treated as being located in a rural area that has had an active reclassification from urban to rural status; and has elected to convert to a hospital that:

1. Is enrolled as an REH with the Centers for Medicare and Medicaid Services (CMS) until:

(i.) Such time as the facility elects to convert back to its prior designation as a CAH or a subsection (d) hospital, as defined in Section 1886(d)(1)(B) of the Social Security Act, as codified at 42 U.S.C. § 1395ww; or

(ii.) The facility does not meet the requirements applicable to an REH, as determined by the Secretary of the U.S. Department of Health and Human Services.

2. Has no more than 50 beds as of December 27, 2020. For purposes of conversion to an REH, the bed count will be determined by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period;

3. Is restricted to the provision of outpatient services, as defined in paragraph (l) herein;

4. Has in effect a transfer agreement with a Medicare-certified hospital, either in the state of Alabama, or in a bordering state, that is designated as a Level I or Level II trauma center;

5. Meets all current licensure requirements set forth by the Board;

6. Meets the requirements of a staffed emergency department, as set forth herein;

7. Meets the federal conditions of participation applicable to REHs under CMS regulations; and

8. Submits a detailed transition plan that lists the specific services that the REH will retain, modify, add, and/or discontinue upon conversion and a description of the services that it intends to furnish on an outpatient basis as an REH.

Facilities that were enrolled as critical access hospitals or rural hospitals with not more than 50 beds as of December 27, 2020, and then subsequently closed after that date, would also be eligible to seek REH designation if they re-enroll in Medicare and meet all of the conditions of participation and licensure requirements for REHs, including an initial onsite survey by the Department.

(w) "Rural Emergency Hospital Services" means the following services furnished by an REH that do not exceed an annual per patient average of 24 hours in the REH:

1. Emergency department services, observation care, and other outpatient and medical services in which the average length of patient stay does not exceed 24 hours. The time calculation for this determination begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH (which occurs when the physician or other appropriate clinician has signed the discharge order or at the time the outpatient service is completed and documented in the medical record).

2. The services provided shall not include any acute care inpatient services, except for the furnishing of post-REH or post-hospital extended care services in the case where the REH includes a distinct part unit of the facility that is licensed as a skilled nursing facility.

(x) "Staffed Emergency Department" means:

1. At a minimum, the emergency department (ED) is physically staffed 24 hours a day, 7 days a week by a physician, an NP, or a PA competent in the skills needed to address emergency medical care and able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

2. The REH must have a professional health care staff consisting of one or more physicians, and may include one or more PAs, NPs, or Clinical Nurse Specialists. Applicable staffing and staffing responsibilities under CMS regulations are met.

(i.) An RN, Clinical Nurse Specialist, or LPN must be on duty whenever the REH has one or more patients receiving emergency care or observation care.

(ii.) A physician must be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH, and is available through direct telephone or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(iii.) The REH must have a physician, a PA, or NP with training or experience in emergency care on call at all times and immediately available by telephone and available onsite within 30 minutes.

(iv.) Whenever a patient is placed in observation care at the REH by an NP or PA, a physician on the staff of the REH is notified of the patient's status.

3. An REH shall be in compliance with the CAH conditions of participation, as they relate to emergency services provided by CAHs, as well as the hospital emergency services requirements, as determined by CMS to be applicable.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.02 The License.

(1) Classifications of Licenses. Each REH shall be licensed pursuant to the regulations adopted herein. All licenses are granted for the calendar year and shall expire on December 31 unless renewed by the owner for the succeeding year.

(a) Unrestricted License. An unrestricted license may be granted by the Board after it has determined that the REH is willing and capable of maintaining compliance with these rules.

(b) Probational License. At its discretion, the Board may grant a probational license when it determines that both of the following conditions exist:

1. The REH has engaged in one or more deficient practices which are serious in nature, chronic in nature, or which the REH has failed to correct; and

2. The REH's current governing authority has demonstrated the capability and willingness to correct cited problems and to maintain compliance.

(c) A probational license shall be granted for a specific period which may be extended but which shall in no case exceed 1 year.

(2) Application.

(a) Application. An applicant for initial licensure as an REH shall provide all information on the application form prescribed by the Department, including all information required by law, these rules, and the policies and procedures of the Department, and shall submit such additional information as shall be required by the Department in its discretion to demonstrate that the applicant has the ability and the willingness to comply with these rules.

1. Each application shall include a detailed transition plan that lists the specific services that the REH will retain, modify, add, and/or discontinue upon conversion and a description of the services that it intends to furnish on an outpatient basis as an REH. The transition plan shall also address the REH's functional plans for utilizing spaces formerly designated for inpatient beds.

2. Each application shall be signed by a person authorized to bind the applicant to the representations in the application and any supporting documentation.

(b) Fee. An initial license application, an application for license renewal, or an application for a change in ownership, shall be accompanied by the application fee specified in §22-21-24, <u>Code of Ala. 1975</u>. An application for a name change is not subject to a license application fee. An application fee is non-refundable. Any application fee submitted in the incorrect amount shall nevertheless be deposited. If the fee submitted is too large, a refund for the difference shall be processed using the Department's usual procedures. If the fee submitted is too small, the applicant shall be notified and the application shall not be considered until the difference is received. Any application is submitted, the application fee shall be deposited, and the applicant shall be notified in writing of the defects in the application. If the applicant fails to submit all required additional information within 10 working days of the date of the notice, the application shall be denied. The Department may in its discretion extend the deadline for submitting additional information, accompanied by the requisite fee, at a future date.

(c) Name of Facility. Every REH shall have a unique name, which shall include the words "Rural Emergency Hospital." No REH shall change its name without first applying for a change of name approval nor shall it change its name until such approval is granted. The Department may in its discretion deny an initial REH application or an application for a change of name if the Department determines that the proposed name is misleading to the public or that the name is overly similar to the name of an already licensed REH. Separately licensed REHs owned by the same governing authority may have names that are similar to one another and distinguished from one another in some other manner, such as a geographic description. If an initial REH application is denied under this rule provision, the applicant shall be provided a reasonable period of time to submit a revised application with a different name.

(d) How to Obtain Applications. Information on how to obtain applications and where to submit applications can be found on the Department's website at http://www.adph.org.

(3) Licensing.

(a) License. If an applicant submits a timely and complete application accompanied by the appropriate license fee and any supporting documentation that may be required by the Department, and if the Department is satisfied on the basis of the application that the applicant is willing and capable of compliance with these rules, and if granting such a license would not violate any other state or federal law or regulation, then the Department, as agent for the Board, may grant a license to the applicant. All licenses granted shall expire at midnight on December 31 of the year in which the license is granted. The Department, as agent for the Board, may deny a license. A license shall only be valid at the licensed premises and for the business entity licensed. It is a condition of licensure that the licensee shall continuously occupy the licensed premises and keep its ED open to the public 24 hours a day, 7 days a week. If an REH fails to remain open and fully staffed as required for 30 consecutive days, its license shall become void. If a licensee abandons the licensed premises, the license shall immediately become void. Before a facility which has closed may be relicensed, a new license application is required.

(b) License Renewal. Licenses may be renewed by the applicant as a matter of course upon submission of a completed renewal application and payment of the required fee. When the Department has served written notice on an REH of its intent to revoke or downgrade the license, a renewal application shall be filed but does not affect the proposed adverse licensure action.

(c) License Certificate. A license certificate shall be issued by the Department to every successful initial licensure applicant and to every successful renewal applicant. It shall set forth the name and physical address of the REH, the name of the governing authority, the type of hospital, and the expiration date of the license.

Change of Ownership. An REH license is not transferable. A change of ownership (d)may only occur between hospitals duly licensed in Alabama by the Board. In the event that the legal ownership of the right to occupy an REH's premises is transferred to an individual or entity other than the licensee, the REH's license shall become void and continued operation of the REH shall be unlawful pursuant to §22-21-22, Code of Ala. 1975, and subject to penalties as provided in §22-21-33, Code of Ala. 1975, unless an application for a change of ownership has been submitted to and approved by the Department prior to the transfer of legal ownership. An application for change of ownership shall be submitted on the form prescribed by the Department, shall be accompanied by the requisite application fee set forth in §22-21-24, Code of Ala. 1975, and shall be subject to the same requirements and considerations as are set forth above for initial license applications. An application for a change of ownership shall be submitted and signed by the prospective new licensee, or its agent, and also either signed by the current licensee or its agent, or accompanied by a court order demonstrating that the current licensee has been dispossessed of the legal right to occupy the premises and that the prospective new licensee has been awarded the legal right to occupy the premises. Upon approval of a change of ownership, the Department shall notify the current licensee and the new license applicant and shall issue a license certificate to the new licensee.

(e) Change of Name. An REH may apply for a change of name by submitting a completed application on a form prescribed by the Department. There is no application fee for a change of name application. Upon approval of a change of name, the Department shall notify the licensee and shall issue a revised license certificate to the licensee, which may be predicated on the return of the old license certificate.

(f) Relocation. An REH license is valid only at the premises stated on the most recent license application or renewal application, and recited as a physical address on the current REH license certificate. Prior to physically relocating an REH, plans and specifications shall be submitted for review and approval to the Department in accordance with the Board's Rules for Submission of Plans and Specifications for Health Care Facilities, Chapter 420-5-22, Ala. Admin. Code. The REH shall submit a relocation application to the Department on a form prescribed by the Department. On relocation, the REH must maintain rural status or continue to be located in an area that has been designated or reclassified as rural in accordance with CMS regulations. Upon approval of a change of address, the Department shall notify the licensee and shall issue a revised license certificate to the licensee, which may be predicated on the return of the old license certificate.

(g) Denial and Revocation of a License.

1. The Board may deny a license to any applicant or revoke the license to operate an REH on grounds of insufficient evidence of the willingness or ability to comply with §§22-21-20 through 22-21-34, <u>Code of Ala. 1975</u>, or these rules, including the reasons justifying denial or revocation of a license as set out in the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

2. Hearing procedures concerning the denial or revocation of a license shall be governed by the provisions of the Alabama Administrative Procedure Act, §41-22-1, et seq., <u>Code of Ala. 1975</u>, and the Board's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

(4) Failure to Renew a License. Any licensee who fails to renew a license on or before the close of business on the last business day in December shall be assessed a late fee equal to the amount of the original license fee. A license may only be renewed with the payment of a late fee before the close of business on the last business day in January of any calendar year. A license which has not been renewed by the end of January has expired and shall be void.

(5) Compliance with federal, state, and local laws. The REH shall be in compliance with all applicable federal, state, and local laws.

(a) Licensing of Staff. Staff of the facility shall be currently licensed, certified, or registered in accordance with applicable laws.

(b) Compliance with Other Laws. The REH shall comply with laws relating to fire and life safety, sanitation, communicable and reportable diseases, Certificate of Need review and

approval, reporting of health care acquired infections, adverse event reporting, and other relevant health and safety requirements. If an REH utilizes the services of a clinical laboratory located outside the state of Alabama, the REH shall ensure that, in connection with any work performed for the REH, the laboratory complies with the requirements for the reporting of notifiable diseases to the Department, as set forth in state law and the rules of the Board.

(6) An REH shall promptly notify the Department in writing when there is any change in its accrediting organization or deemed status.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.03 The Governing Authority.

(1) An REH shall have an effective governing authority that is legally responsible for the conduct of the REH as an institution and shall provide administrative oversight for the care and services of the REH. The governing body must:

(a) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(b) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

- (c) Ensure that the medical staff has bylaws;
- (d) Approve medical staff bylaws and other medical staff rules and regulations;

(e) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; and

(f) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

1. Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The REH grants privileges in accordance with recommendations from qualified medical personnel.

2. Medical staff privileges must be periodically reappraised by the REH. The scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.

3. If the REH assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

(g) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the REH dependent solely upon certification, fellowship, or membership in a specialty body or society.

(2) Contracted services. The governing authority shall be responsible for services furnished in the REH whether or not they are furnished under contracts. The governing authority shall ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the REH to maintain compliance with the requirements of these rules.

(a) The governing authority shall ensure that the services performed under a contract are provided in a safe and effective manner.

(b) The REH shall maintain a list of all contracted services, including the scope and nature of the services provided.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.04 Patient Rights.

(1) The REH shall have an obligation to protect and promote the rights of each patient and shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code, with the exception of the training requirements for restraint and seclusion, and the additional requirements set forth herein.

(2) An REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must meet the following requirements:

(a) Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section.

(b) Inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time.

(c) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(d) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

(3) The patient has the right to safe implementation of restraint or seclusion by trained staff.

(a) The REH must provide patient-centered competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion.

(b) The training must include alternatives to the use of restraint/seclusion.

(4) REHs must report deaths associated with the use of seclusion or restraint to CMS as required.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.05 Personnel.

(1) The REH shall have personnel management as a section of the hospital's personnel system. The REH shall be adequately staffed at all times to meet the needs of the patient population served. At a minimum, the ED must be physically staffed 24 hours a day, 7 days a week by a physician, an NP, or a PA competent in the skills needed to address emergency medical care and able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

- (2) Staff qualifications for REHs.
- (a) The REH medical director shall be:
- 1. Either

(i.) Board certified by the American Board of Emergency Medicine, the American Osteopathic Board of Emergency Medicine, the American Board of Physician Specialties, or a like credentialing organization for emergency medicine; or

(ii.) Certified or Board eligible to sit for the examination of one of the following boards: internal medicine, family medicine, or surgery. The physician shall also hold a current certificate from each of the following approved programs: Advanced Coronary Life Support; Advanced Trauma Life Support; and Advanced Pediatric Life Support; and must have at least 3 years of full-time clinical experience in emergency medicine within the past 5 years. Physicians meeting the aforesaid criteria with at least 1 but fewer than 3 years of full-time clinical experience in emergency medicine must also hold a certificate of completion for all modules of the Emergency Medicine Core Training (EMCT) Program. Physicians who are not board certified in emergency medicine will need to annually maintain one-half of their Alabama State Continuing Medical Education credits in emergency medicine. 2. Competent in management and administration of clinical services in an emergency department.

3. Knowledgeable about emergency medical services (EMS) operations and the regional EMS network.

4. Responsible for assessing and making recommendations to the hospital's credentialing body related to the qualifications of REH physicians and the clinical privileges granted to REH practitioners.

5. Responsible to provide medical direction for the REH's health care activities and consultation for, and medical supervision of, the health care staff and for assuring that the clinical staff are continuously qualified, competent, and supervised in the emergency care of patients.

(i.) In conjunction with the PA and/or NP staff member(s), the REH medical director shall participate in developing, executing, and periodically reviewing the REH's written policies governing the services it furnishes.

(ii.) In conjunction with the PA and/or NP staff members, the REH medical director shall periodically review the REH's patient records, provide medical orders, and provide medical care services to the patients of the REH.

(b) Each REH physician shall be individually credentialed by the hospital medical staff.

(c) A physician must be present onsite for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH, and must be available through direct telephone or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(d) The REH must have a physician, a PA, or an NP with training or experience in emergency care on call at all times and immediately available by telephone and available onsite within 30 minutes. An NP working onsite without a physician present must:

1. Be certified as a family nurse practitioner (certified to treat both adult and pediatric patients);

2. Have 4000 hours of advanced practice experience in the collaborating physician's practice specialty area;

3. Have had competency certified by the collaborating physician for skills in the protocol, to include intubation;

4. Have current certifications in Advanced Coronary Life Support, Advanced Life Support in Obstetrics, and Pediatric Advanced Life Support.

(e) A PA working in the REH must:

1. Have had competency certified by the supervising physician for skills in the protocol;

2. Have current certifications in Advanced Coronary Life Support, Advanced Life Support in Obstetrics, and Pediatric Advanced Life Support.

(f) The Director of Nursing Services in the REH shall be a registered nurse with an active and unencumbered license from the Alabama Board of Nursing and shall direct all nursing services and all nursing support personnel. The Director of Nursing must:

1. Have 2 years of experience as an emergency room RN.

2. Provide evidence of competent management and administration of clinical services in an ED.

3. Ensure nursing and support staff are appropriately educated and qualified.

4. Meet the additional qualifications for RNs in the subparagraphs below.

(g) Each RN in an REH shall:

1. Provide evidence of at least 1 year of experience as a staff nurse in an acute care facility.

2. Have successfully completed the Emergency Nursing Pediatric Course/Trauma Nursing Core Course (ENPC/TNCC) and have current certifications in Advanced Coronary Life Support and Pediatric Advanced Life Support.

3. For practice beyond basic nursing education, demonstrate successful completion of an organized program of study and facility-based validated competency which assesses the nurse's knowledge, skills, and ability to perform emergency nursing procedures safely and to manage patient complications.

(3) At least one licensed RN meeting the above-stated requirements shall be onsite at the REH at all times.

(4) At all times, at least one certified and registered radiology technologist shall be onsite at the REH or immediately available by telephone or electronic communication and available onsite within 30 minutes.

(5) At all times, at least one person qualified to perform laboratory testing at the level of laboratory services provided onsite by the REH shall be onsite at the REH or immediately available by telephone or electronic communication and available onsite within 30 minutes.

(6) Each REH shall have a fulltime administrative director who directs the daily administrative operations of the REH, ensures the employees and staff are adequately trained, and provides oversight of the maintenance of the REH, coordination of patient safety, and quality improvement programs and activities.

(7) Personnel Records. Each REH shall maintain a personnel record for each employee. At a minimum, the record shall include an application for employment that contains information regarding the applicant's education, training, experience, and if applicable, registration, certification, or licensure information.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.06 Physical Environment.

(1) An REH shall be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment of patients.

(2) An REH shall comply with the applicable requirements of the *Guidelines for Design and Construction of Health Care Facilities*. Facilities or portions of facilities built under the currently adopted codes shall comply with the requirements for New Health Care Occupancies in the currently adopted *National Fire Protection Association 101, Life Safety Code*. Facilities or portions of facilities built under previously adopted editions of the codes shall comply with the requirements for Existing Health Care Occupancies in the currently adopted *Life Safety Code*.

(3) Submission of Plans and Specifications. Any REH planning to have an addition or alteration of space and or conversion of space for other use shall provide plans and specifications to the Department in accordance with the Board's Rules for Submission of Plans and Specifications for Health Care Facilities, Chapter 420-5-22, Ala. Admin. Code.

(a) Minor alterations and remodeling which do not affect the structural integrity of the building, which do not alter functional operation, which do not affect fire safety, and which do not add new services over those for which the facility is licensed, need not be submitted for approval.

(b) Inspections. The Board and its authorized representatives shall have access to all facilities for inspection.

(4) Remodeling.

(a) The remodeled area of existing facilities shall be upgraded to comply with the current requirements for new construction.

(b) Any remodeling to existing facilities shall not diminish the level of safety which existed prior to the start of the work.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.07 Patient Transport or Referral.

(1) Each REH shall have in effect an agreement with at least one Medicare-certified hospital that is a Level I or Level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. The certified hospital receiving the REH's patients must have a valid and current license from the Board, or from the comparable state agency or licensing body of a bordering state, and be designated by the applicable state as Level I or Level II trauma center or verified by the American College of Surgeons as a Level I or Level II trauma center. An REH may have additional transfer agreements in effect with hospitals which are not designated as a Level I or Level II trauma center, provided that such hospitals are licensed by the Board, or the comparable state agency or licensing body of a bordering state, and such hospitals do not serve as the referring or transfer hospital for patients requiring emergency medical care beyond the capabilities of the REH, for purposes of this rule. The REH shall endeavor to facilitate an agreement with the Medicare-certified hospital that is a Level I or Level II trauma center that is in the closest proximity to the REH.

(2) The REH shall transfer or refer patients when necessary, along with all necessary medical information, to appropriate licensed facilities, agencies, or outpatient services for follow up or ancillary care. In no event shall an REH knowingly refer a patient to an unlicensed health care facility in violation of §22-21-33(b), <u>Code of Ala. 1975</u>.

(3) For transportation out of a facility, if a patient is unable to ride in an upright position or if such patient's condition is such that he or she needs observation or treatment by EMS personnel, or if the patient requires transportation on a stretcher, gurney or cot, the facility shall arrange or request transportation services only from providers who are EMS providers licensed by the Board. For the purposes of this rule, an upright position means no more than 20 degrees from vertical. If such patient is being transported to or from a health care facility in another state, transportation services may be arranged with a transport provider licensed as an EMS provider in that state.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.08 Medical Staff.

(1) The members of the REH medical staff shall conform to the medical staff bylaws and rules and regulations of the hospital, as approved by the governing authority, and shall be responsible for the quality of medical care provided to patients by the hospital.

(2) The medical staff must be composed of physicians. In accordance with state law, including scope-of-practice laws, the medical staff may also include other categories of physicians and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(a) The medical staff must periodically conduct appraisals of its members.

(b) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) The medical staff must be organized in a manner approved by the governing body.

(a) If the medical staff has an executive committee, a majority of the members of the committee must be physicians.

(b) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following: an individual physician; a doctor of dental surgery or dental medicine, when permitted by state law; or a doctor of podiatric medicine, when permitted by state law.

(4) If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified REH must demonstrate that:

(a) The medical staff members of each separately certified REH in the system (that is, all medical staff members who hold specific privileges to practice at that REH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective REH;

(b) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified REH (that is, all medical staff

members who hold specific privileges to practice at that REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their REH;

(c) The unified and integrated medical staff is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(d) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

(5) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the agreement must be written and specify that it is the responsibility of the governing body of the distant-site hospital to meet the requirements of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with CMS regulations, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(6) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the written agreement must specify that the distant-site telemedicine entity is a contractor of services to the REH and as such, furnishes the contracted services in a manner that permits the REH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services may, in accordance with CMS regulations, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such REH's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

(7) The governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (2) and (3) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital or telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement, that all of the following provisions are met:

(a) The distant-site hospital providing the telemedicine services is a Medicare participating hospital.

(b) The medical staff of the distant-site telemedicine entity providing the telemedicine services meets all of the above-listed standards of this section.

(c) The individual distant-site physician or practitioner is privileged at the distant-site hospital or telemedicine entity providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital or telemedicine entity.

(d) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving the telemedicine services is located.

(e) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital or telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH has received about the distant-site physician or practitioner.

(8) The quality and appropriateness of the diagnosis and treatment furnished by NPs and PAs at the REH must be evaluated by a member of the REH staff who is a physician or by another physician under contract with the REH.

(9) The quality and appropriateness of the diagnosis and treatment furnished by physicians at the REH must be evaluated by one of the following:

(a) One Quality Improvement Organization (QIO) or equivalent entity.

(b) In the case of distant-site physicians and practitioners providing telemedicine services to the REH patients under an agreement between the REH and a distant-site hospital, the distant-site hospital; or

(c) In the case of distant-site physicians and practitioners providing telemedicine services to the REH patients under a written agreement between the REH and a distant-site telemedicine entity, one QIO or equivalent entity.

(10) The REH staff will consider the findings of the evaluations and make any necessary changes.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.09 <u>Quality Assurance or Quality Assessment and Performance Improvement</u> (QAPI) Program.

(1) The REH shall participate in the QAPI Program and shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code, with the exception of the provisions governing performance improvement projects. The REH must maintain and demonstrate evidence of its QAPI Program for review by the Department.

(2) If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of 2 or more hospitals, CAHs, and/or REHs, the system governing authority can elect to have a unified and integrated QAPI Program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all the requirements of this section. Each separately certified REH subject to the system governing authority must demonstrate that:

(a) The unified and integrated QAPI Program is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH; and

(b) The unified and integrated QAPI Program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI Program has mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.10 Nursing Services.

(1) The REH shall have an organized nursing service that provides 24-hour nursing services that meets the needs of the patients. The nursing services shall be furnished and supervised by an RN. An RN, Clinical Nurse Specialist, or LPN must be on duty whenever the REH has one or more patients receiving emergency care or observation care.

(2) Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice.

(3) The director of the nursing service must be a licensed RN by the Alabama Board of Nursing. The individual 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 REH.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.11 Infection Control.

(1) The REH shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and investigation of infections and communicable diseases supervised and administered by the hospital. The REH shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

(2) An individual (or individuals) qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, must be appointed by the governing authority as the leader(s) of the infection prevention and control and antibiotic stewardship programs, based on the recommendations of medical staff leadership and pharmacy leadership.

(3) The facility-wide antibiotic stewardship program:

(a) Demonstrates coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI Program, the medical staff, nursing services, and pharmacy services;

(b) Documents the evidence-based use of antibiotics in all departments and services of the REH; and

(c) Documents any improvements, including sustained improvements, in proper antibiotic use.

(4) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(5) The antibiotic stewardship program reflects the scope and complexity of the services furnished by an REH.

(6) The leader(s) of the antibiotic stewardship program is responsible for:

(a) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(b) All documentation, written or electronic, of antibiotic stewardship program activities.

(c) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the REH's infection prevention and control and QAPI Programs, on antibiotic use issues.

(d) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(7) If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of 2 or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that:

(a) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;

(b) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration;

(c) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed; and

(d) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the REH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.12 Medical Record Services.

(1) The REH shall have a medical record service that has administrative responsibility for medical records and maintains the medical records system in accordance with written policies and procedures. Each REH shall also maintain any picture archiving and communications system (PACS) obtained prior to conversion, which provides for the timely and efficient storage, transmission, and retrieval of digital medical images.

(2) Each REH shall maintain a register or log of all patients who present to the REH for treatment or services.

(3) For each patient receiving health care services, the REH must maintain a record that includes, as applicable:

(a) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(b) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(c) All orders of physicians or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(d) Dated signatures of the physician or other health care professional.

(e) All orders, including verbal orders, shall be dated, timed, and authenticated by the ordering practitioner in accordance with hospital policy, but no longer than 30 days after entry.

(4) The REH must maintain the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(a) The REH must have written policies and procedures that govern the use and removal of records from the REH and the conditions for the release of information.

(b) The patient's written consent is required for release of information not required by law.

(c) The records must be retained for at least 7 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

(5) If the REH utilizes an electronic medical records system or other electronic administrative system, which is conformant with applicable CMS rules, then the REH must demonstrate that:

(a) The system's notification capacity is fully operational and the REH uses it in accordance with all state and Federal statutes and regulations applicable to the REH's exchange of patient health information.

(b) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(c) To the extent permissible under applicable federal and state laws and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of the patient's registration in the REH's ED.

(d) To the extent permissible under applicable federal and state laws and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately, prior to, or at the time the patient's discharge or transfer from the REH's ED.

(e) The REH makes a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

- 1. The patient's established primary care practitioner;
- 2. The patient's established primary care practice group or entity; or

3. Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for their care.

(6) The REH shall maintain a plan to transfer all records to another facility in the event the REH ceases operation.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.13 Food and Dietetic Services.

(1) The REH shall have appropriate food and beverages available for the patients and shall be responsible for meeting the nutritional needs of patients.

(2) The REH may, at its discretion, make available food and beverage service to staff and visitors. The available food and beverage service areas must be maintained in a clean and sanitary manner. (3) Facilities admitting patients for periods in excess of 12 hours shall meet the requirements of Ala. Admin. Code r. 420-5-2-.04(4)(e), and the following requirements, which are in addition to and not in lieu of requirements set forth elsewhere in these rules:

(a) Dietary Services.

1. In the event that meals are prepared in the facility, the facility shall have organized dietary services that are directed and staffed by adequate qualified personnel, including a qualified food service manager and consultation by a licensed registered dietician as required to meet the dietary needs of the patients. However, a hospital that has a contract with an outside food management company may meet the requirements of this rule 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 rule and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

2. In the event that food is prepared outside the facility, such food preparation shall be performed only by facilities which meet the requirements of Alabama Administrative Code, Chapter 420-3-14, Food Service Sanitation. In addition, the REH must provide a food preparation area with:

- Double sink, if disposables are not utilized at all times.
- Microwave oven.
- Refrigerator.
- Hand-washing sink.
- Counter space.
- Towel cabinet.
- Soap dispenser.
- Garbage cans with cover.
- Coffee maker.
- Storage area for silverware and cutlery, if disposables are not utilized at all times.

3. In all facilities, a floor pantry or diet kitchen readily available to the nursing unit shall be provided. The equipment provided shall be sufficient to furnish ice and between-meal nourishment to patients.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.14 Emergency Services.

(1) The REH shall meet the emergency needs of its patients in accordance with acceptable standards of practice and organized under the direction of a qualified member of the medical staff. There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(2) The REH must meet the requirements for CAHs specified under CMS regulations, with respect to:

- (a) Twenty-four (24) hour availability of emergency services;
- (b) Equipment, supplies, and medication;
- (c) Blood and blood products;
- (d) Personnel;
- (e) Coordination with emergency response systems.

(3) Each REH shall meet the Emergency Medical Treatment and Labor Act (EMTALA) statute codified at § 1867 of the Social Security Act (42 USC § 1395dd), the accompanying regulations, and the related requirements, as a required condition of participation for CMS certification.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.15 Pharmaceutical Services.

The REH shall have pharmaceutical services that meet the needs of its patients and shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code, and all applicable federal and state law and rules governing the maintenance and provision of pharmaceutical products and services.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.16 Radiologic Services.

The REH shall maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, the therapeutic, as well as the diagnostic services, must be furnished by the REH and provided by personnel qualified under state law. All radiologic services shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.17 Laboratory Services.

(1) The REH shall have basic laboratory services essential to the immediate diagnosis and treatment of the patient, consistent with nationally recognized standards of care for emergency services. Laboratory services shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code. Specialized laboratory studies which are required as medically necessary at the time that the patient presents to the REH, but not available in the laboratory facilities on site, shall be sent to another licensed hospital or other appropriate, certified laboratory for processing. The REH shall have policies and procedures for this arrangement which include review and communication of results to the appropriate individual.

(2) The REH's laboratory shall maintain a current federal Clinical Laboratory Improvement Amendments (CLIA) number and certificate.

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

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.18 Nuclear Medicine Services.

If the REH provides nuclear medicine services, those services shall meet the needs of the patients in accordance with acceptable standards of practice and shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.19 Respiratory Care Services.

(1) The REH shall meet the needs of its patients for respiratory care services in accordance with acceptable standards of practice and shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

(2) Respiratory care services may be provided by RNs who are properly trained and supervised. An REH is required to have respiratory therapy staff on duty or on call to provide consultation in appropriate circumstances based on the scope of services provided by the REH and the patient population it serves.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.20 Additional Outpatient Medical and Health Services.

(1) If the REH provides outpatient medical and health services in addition to providing emergency services and observation care, those services shall meet the needs of the patients in accordance with acceptable standards of practice and shall be governed by the applicable Board rules for each service provided.

(2) The REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. Each provider of the outpatient and medical health diagnostic and therapeutic services offered by the REH shall be individually credentialed by the REH's governing authority and shall be governed by the applicable rules for that provider's licensing authority while providing the service.

(3) If the REH provides outpatient and medical health diagnostic and therapeutic items and services, those items and services must align with the health needs of the community served by the REH. If the REH provides outpatient medical and health services in addition to providing emergency services, the REH must:

(a) Provide items and services based on nationally recognized guidelines and standards of practice.

(b) Have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate.

(c) Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences.

(d) Have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH.

(e) Have qualified, credentialed personnel approved by the REH's governing authority, providing these services and available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(f) For any specialty services offered at the REH, the REH must have a physician, NP, or PA providing services with experience and training in the specialty service area and in accordance with their scope of practice.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.21 Surgical Services.

(1) If the REH provides outpatient surgical services, surgical procedures must be performed in a safe manner by qualified and credentialed practitioners who have been granted clinical privileges by the REH's governing authority in accordance with the REH's approved policies and procedures and the state scope of practice laws. Each provider of the surgical services offered by the REH shall be individually credentialed by the REH's governing authority and shall be governed by the applicable rules for that provider's licensing authority while providing the service and by the applicable provisions of the Board's Rules for Ambulatory Surgical Treatment Facilities, Chapter 420-5-2, Ala. Admin. Code. Surgery shall be performed only by a physician; a doctor of dental surgery or dental medicine; or a doctor of podiatric medicine.

(2) A qualified practitioner, as specified in paragraph (1) above, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed. A qualified practitioner, as specified in paragraph (3) below, must examine each patient before surgery to evaluate the risk of anesthesia. Before discharge from the REH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (3) below.

(3) Anesthesia shall be administered in accordance with the REH's approved policies and procedures and within state scope of practice laws. Anesthesia shall be administered to patients only by an anesthesiologist, anesthesiologist assistant, doctor of dental surgery or dental medicine, doctor of podiatric medicine, CRNA, or a physician deemed qualified by the facility's medical director. CRNAs must administer anesthesia under the direct physical supervision of a licensed physician, dentist or podiatrist, or in coordination with a licensed physician, dentist or podiatrist who is immediately available. Anesthesiologist assistants must administer anesthesia under the direct supervision of an anesthesiologist. After the administration of anesthesia, patients shall remain under the physical observation of a physician, RN, or LPN (the LPN must be directly supervised by an RN) until the patient is sufficiently alert and able to summon aid. Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.22 Discharge Planning.

The patient or their representative shall be provided written discharge instructions regarding follow up referrals/appointments, medication management and procurement, durable medical equipment, availability of community resources and other identified needs at the time of discharge. Any discharge planning evaluation or discharge plan must be developed by, or under the supervision of, an RN, social worker, or other appropriately qualified personnel. A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate services following those furnished by the REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services. An REH's provisions regarding discharge planning shall be governed by the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.23 Emergency Preparedness.

(1) The REH shall develop and implement a comprehensive plan that complies with all applicable federal, state, and local emergency preparedness requirements to ensure that the safety and wellbeing of patients are assured during emergency situations. An REH's emergency preparedness plan must include provisions for emergency preparedness, risk assessment, communication, and an emergency preparedness training and testing program. All aspects of the plan must be reviewed and updated at least every 2 years and meet the emergency preparedness requirements of the Board's Rules for Hospitals, Chapter 420-5-7, Ala. Admin. Code.

(2) At a minimum, the policies and procedures must address the following:

(a) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to:

- 1. Food, water, medical, and pharmaceutical supplies; and
- 2. Alternate sources of energy to maintain:

(i.) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(ii.) Emergency lighting.

(iii.) Fire detection, extinguishing, and alarm systems; and

(iv.) Sewage and waste disposal.

(b) A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the REH must document the specific name and location of the receiving facility or other location.

(c) Safe evacuation from the REH, which includes the following:

1. Consideration of care and treatment needs of evacuees.

2. Staff responsibilities.

3. Transportation.

4. Identification of evacuation location(s), and

5. Primary and alternate means of communication with external sources of assistance.

(d) A means to shelter in place for patients, staff, and volunteers who remain in the REH.

(e) A system of medical documentation that does the following:

1. Preserves patient information.

2. Protects confidentiality of patient information, and

3. Secures and maintains the availability of records.

(f) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency.

(g) The role of the REH under a waiver declared by the U.S. Secretary of Health and Human Services and, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(3) The REH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth hereinabove. The REH must do all of the following:

(a) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(b) Provide emergency preparedness training at least every 2 years.

(c) Maintain documentation of all emergency preparedness training.

(d) Demonstrate staff knowledge of emergency procedures.

(e) If the emergency preparedness policies and procedures are significantly updated, the REH must conduct training on the updated policies and procedures.

(4) The REH must conduct exercises to test the emergency plan at least annually. The REH must do the following:

(a) Participate in a full-scale exercise that is community-based every 2 years.

1. When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

2. If the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(b) Conduct an additional exercise at least every 2 years, opposite the year the fullscale or functional exercise is conducted, that may include, but is not limited to the following:

1. A second full-scale exercise that is community-based, or an individual, facilitybased functional exercise; or

2. A mock disaster drill; or

3. A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(c) Analyze the REH's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

(5) The REH must implement emergency and standby power systems based on the emergency plan.

(a) The emergency generator must be located in accordance with the location requirements found in the Health Care Facilities Code (National Fire Protection Association

(NFPA) 99 and Technical Interim Amendments (TIA) 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(b) The REH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(c) REHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(6) If an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must:

(a) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(b) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(c) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.

420-5-23-.24 Skilled Nursing Facility Distinct Part Unit.

(1) An REH may include a unit of the facility that is a distinct part licensed and certified as a skilled nursing facility to furnish post-hospital extended care services and be considered a hospital with less than 50 beds for purposes of the exception to the payment limit for rural health clinics under Section 1833(f).

(2) If the REH provides skilled nursing facility services in a distinct part unit, the services furnished by the distinct part unit must comply with the requirements of participation for long-term care facilities specified in the CMS rules and be governed by the Board's Rules for Nursing Facilities, Chapter 420-5-10, Ala. Admin. Code.

Author: Dana H. Billingsley Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq. History: New Rule: Filed August 21, 2023; effective October 15, 2023.