

ALABAMA STATE COMMITTEE OF PUBLIC HEALTH
 DIVISION OF LICENSURE AND CERTIFICATION
 ADMINISTRATIVE CODE

CHAPTER 420-5-7
 HOSPITALS

TABLE OF CONTENTS

420-5-7-.01	General Provisions
420-5-7-.02	The License
420-5-7-.03	Classification Of Hospitals
420-5-7-.04	The Governing Authority
420-5-7-.05	Patient Rights
420-5-7-.06	Personnel
420-5-7-.07	Physical Environment
420-5-7-.08	Patient Transport
420-5-7-.09	Medical Staff
420-5-7-.10	Quality Assurance Or Quality Assessment And Performance Improvement (QAPI)
420-5-7-.11	Nursing Services
420-5-7-.12	Infection Control
420-5-7-.13	Medical Record Services
420-5-7-.14	Food Dietetic Services
420-5-7-.15	Emergency Services
420-5-7-.16	Pharmaceutical Services
420-5-7-.17	Surgical Services
420-5-7-.18	Anesthesia Services
420-5-7-.19	Radiologic Services
420-5-7-.20	Laboratory Services
420-5-7-.21	Nuclear Medicine Services
420-5-7-.22	Rehabilitation Services
420-5-7-.23	Respiratory Care Services
420-5-7-.24	Outpatient Services
420-5-7-.25	Discharge Planning
420-5-7-.26	Psychiatric Hospitals
420-5-7-.27	Emergency Preparedness
420-5-7-.28	Obstetrics And Newborn (Repealed)
420-5-7-.15 (Repealed)	Utilization Review (Repealed)
420-5-7-A	Appendix A Information On The Application Process for Hospitals

420-5-7-.01

General Provisions.

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

(2) Definitions

(a) Authorized Bed Capacity means the number of beds a hospital has available for inpatient care. A hospital may by application designate its authorized bed capacity, not to exceed its licensed bed capacity. The term, "Authorized Bed Capacity," shall exclude beds intended for ancillary usage such as labor beds, recovery room beds and stretchers, and bassinets for newborn infants. The authorized bed capacity is also the maximum daily census that a hospital may have admitted in an in-patient capacity. A hospital shall at all times have in place the actual beds and all necessary ancillary equipment for individual patient care equal to the number of its authorized bed capacity. A hospital's authorized bed capacity may be the same as its licensed bed capacity, or it may be some smaller number, but its authorized bed capacity may never exceed its licensed bed capacity.

(b) Board or State Board of Health means the Alabama State Board of Health.

(c) Certified Registered Nurse Anesthetist (CRNA) means a registered nurse who meets the requirements and is approved by the Alabama Board of Nursing to practice as a CRNA.

(d) Clinical Psychologist means a person who holds a doctoral degree in psychology and who is currently licensed in Alabama at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

(e) Department means the Alabama Department of Public Health.

(f) Governing Authority means 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 a hospital, and exercising control over the affairs of said hospital.

(g) Hospital means a health institution planned, organized, and maintained for offering to the public, facilities and beds for use in the diagnosis and treatment of patients

requiring in-patient medical care, out-patient medical care, or other care performed by or under the supervision of physicians due to illness, disease, injury, deformity, abnormality, or pregnancy.

(h) License means the legal authority to operate a hospital as defined above, to admit patients, 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.

(i) License Certificate means a document issued by the Department showing that the entity named on the document is licensed as a hospital. 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.

(j) Licensed Bed Capacity means the number of beds for which the facility has a certificate of need, and has been issued a certificate of licensure by the Department. The term "Licensed Bed Capacity" shall exclude beds intended for ancillary usage such as labor beds, recovery room beds and stretchers, and bassinets for newborn infants.

(k) Licensed Practical Nurse means a person who holds an active license issued by the Alabama Board of Nursing.

(l) Physician means a person currently licensed to practice medicine and/or surgery in Alabama under the provisions contained in current state statutes.

(m) Principal means an individual associated 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;
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 ten percent or more of the governing authority or of any business entity of which the governing authority is a subsidiary.

(n) Registered Nurse means a person who holds an active license issued by the Alabama Board of Nursing.

Author: W. T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed March 20, 1992. **Amended:** Filed May 20, 1994, effective June 24, 1994.

Repealed and New Rule: Filed November 18, 1994; effective December 23, 1994. **Amended:** Filed January 19, 1996; effective February 23, 1996. **Amended:** Filed December 16, 1999; effective January 20, 2000. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.02

The License.

(1) Classifications of Licenses. 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 hospital 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 hospital has engaged in one or more deficient practices which are serious in nature, chronic in nature, or which the hospital has failed to correct.

2. The hospital'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 one year.

(2) Application.

(a) Application. An applicant for initial licensure 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. Each application shall

be signed by the applicant, if the applicant is a natural person, or, if the applicant is not a natural person, shall be signed by a natural person who is 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, an application for an increase in the number of authorized or licensed beds, or an application for a change in ownership, shall be accompanied by the application fee specified in §22-21-24, Code of Ala. 1975. An application for a name change, an application for a decrease in authorized or licensed bed capacity, or an application for a relocation 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 submitted without any fee shall be returned to the applicant. If an incomplete 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. Denial of an application as incomplete shall not prejudice the applicant from submitting a new application, accompanied by the requisite fee, at a future date.

(c) Name of Facility. Every hospital shall have a unique name. No hospital 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 hospital 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 hospital. Separately licensed hospitals 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. No hospital licensed on the date these rules are adopted shall be required to change its name as a result of this rule provision. If an initial hospital 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) Number of Beds. Each application for license shall specify the bed capacity the facility seeks to have approved by the Department.

1. A hospital shall specify on an application for licensure its licensed bed capacity and its designated authorized bed capacity. The designated authorized bed capacity shall not exceed the licensed bed capacity.

2. A hospital shall have available for inpatient care at all times the total number of beds designated as its authorized bed capacity.

3. A hospital desiring to change its authorized bed capacity shall submit an application to the Department.

4. The hospital's license certificate from the Department shall set forth its licensed bed capacity and its authorized bed capacity.

5. No hospital may have licensed beds in excess of those specified on its certificate of need.

6. In the event of a natural disaster or other catastrophic emergency, the Department may grant a temporary bed increase to any hospital for reasons of public health or public safety. A temporary bed increase may be granted only for a specified number and shall expire by its terms after a specific, finite period of time.

(e) How to Obtain Applications. Information on how to obtain applications and where to submit applications is contained in the appendix to these rules.

(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 individual or business entity licensed. It is a condition of licensure that the licensee must continuously occupy the licensed premises and remain open to the public as a hospital, fully staffed and otherwise

capable of admitting and treating patients. If a hospital fails to remain open and staffed as required for 30 days, its license shall become void. If a licensee abandons the licensed premises, the license shall immediately become void.

(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 the hospital 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 hospital, the name of the governing authority, the type of hospital, the expiration date of the license, the hospital's licensed bed capacity, and its authorized bed capacity.

(d) Change of Ownership. A hospital license is not transferrable. In the event that the legal ownership of the right to occupy a hospital's premises is transferred to an individual or entity other than the licensee, the hospital license shall become void and continued operation of the hospital 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. Indicia of ownership of a hospital include the right to hire, terminate, and to determine the compensation and benefits paid to the hospital's administrator and other staff, the right to receive payment from patients and third parties for services provided by the hospital, the right to establish and to change the policies, procedures, and protocols under which the hospital operates,

and the right to overrule operational decisions made by the hospital administrator and other staff.

(e) Change in Bed Capacity. A hospital may apply for a change in licensed bed capacity or authorized bed capacity by submitting a completed application on a form prescribed by the Department and, for a change in licensed bed capacity, accompanied by the fee prescribed in §22-21-24, Code of Ala. 1975, together with such other documentation as the Department may require, which shall include Certificate of Need approval or a letter of non-reviewability if the application is for an increase in the number of licensed beds. Upon approval of a change of bed capacity, 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) Change of Name. A hospital 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. The Department may in its discretion deny 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 hospital. Separately licensed hospitals 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. 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.

(g) Relocation. A hospital 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 hospital license certificate. Prior to physically relocating a hospital, the licensee of the hospital shall submit a relocation application to the Department on a form prescribed by the Department. 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.

(h) Single Campus Requirement. A hospital's campus shall consist of the premises occupied by the hospital's largest building together with all parcels of property that the hospital's governing authority owns or has the legal right to occupy and which are not separated from the remainder of the campus by anything other than a public right of way. All hospital services required by these rules shall be offered on-campus. So long as it does not violate any other law or legal

requirement, a hospital's governing authority may offer any health care services other than a reference laboratory on the hospital campus without the need for additional licensure from the Board, even if such services would require licensure if offered by a free-standing facility. A hospital may, however, elect to seek licensure for such a facility located on its campus. Such services shall remain under the control and supervision of the governing authority. All on-campus facilities and services are subject to the rules of the Board, including applicable life safety code, building, and plan review requirements. If the hospital operates a facility away from its campus that would require separate licensure if not provider-based, such as an end stage renal dialysis center or a rehabilitation center, then that facility must be separately licensed and meet all licensure requirements for that type of facility. A hospital may operate any facility that does not require separate licensure away from its campus, but if the hospital bills Medicare or Medicaid under its hospital provider number for services provided in the off-campus facility, that off-campus facility shall be deemed to be part of the hospital for licensure purposes and shall be subject to the rules of the Board, including applicable life safety code, building, and plan review requirements. No part of a hospital may be more than 35 miles from its campus. Provided, however, that this subsection is not intended to authorize the operation of an off-campus emergency department or multiple non-contiguous hospitals to operate under a single license.

(i) Denial of a License

1. The Board may deny a license to any applicant on grounds of insufficient evidence of the willingness or ability to comply with §§22-21-20 through 22-21-34, Code of Ala. 1975, or these rules, including the following reasons:

(i) The applicant or any principal associated with the applicant has violated any provision of §§22-21-20 through 22-21-34, Code of Ala. 1975.

(ii) The applicant or any principal associated with the applicant has been convicted of engaging in, permitting, aiding, or abetting the commission of an illegal act in the hospital or in any other licensed health care facility.

(iii) The applicant or any principal associated with the applicant has engaged in conduct or practices deemed by the Board to be detrimental to the welfare of the patients of the institution.

(iv) Conduct and practices deemed detrimental to the welfare of patients of a hospital or provide grounds pursuant to this subsection for denial of a license include:

(I) The applicant or an agent authorized by the applicant has deliberately falsified any material information or record submitted as part of the application for licensure.

(II) The applicant has changed its corporate name, charter, entity, or its partnership name or composition to avoid the imposition of liens or court action.

(III) The applicant or any principal associated with the applicant has been convicted of engaging in the physical, mental, or sexual abuse or in the financial exploitation of a patient or patients.

(IV) The applicant or any principal associated with the applicant has operated a health care facility in Alabama or in any other jurisdiction in a manner that resulted in one or more violations of applicable laws or other requirements and as a result caused death, injury, disability, or serious risk of death, injury, or disability to any patient or patients of the facility and such past conduct causes the Department to reasonably believe that granting a license to the applicant would likely be detrimental to the life, health, or safety of prospective patients of the hospital for which licensure is sought.

(V) The applicant or any principal associated with the applicant has been convicted of fraud in this or any other jurisdiction.

(VI) The applicant or any principal associated with the applicant has in the past deliberately falsified records or has otherwise made a deliberate and material misrepresentation of facts to an employee of the Department in an attempt to influence the outcome of a survey or some other regulatory compliance determination by the Department.

(VII) The applicant or any principal associated with the applicant has in the past induced or attempted to induce a subordinate employee to falsify records or to otherwise make a

deliberate and material misrepresentation of facts to an employee of the Department in an attempt to influence the outcome of a survey or some other regulatory compliance determination by the Department.

(VIII) The applicant or any principal associated with the applicant is operating, or has in the past operated, an unlicensed health care facility.

(IX) The applicant or any principal associated with the applicant has at any time been debarred from participation in the Medicare or Medicaid programs.

(X) Other serious misconduct which, in the judgment of the Board, poses a serious risk to patient health or safety.

2. An applicant may appeal the denial of a license pursuant to the provisions of the Alabama Administrative Procedure Act, §41-22-1, et seq., Code of Ala. 1975, and the Board's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

(j) Revocation of a License.

1. The Board may revoke a license to operate a hospital if it finds any of the following:

(i) Violations of any of the provisions of §22-21-20, et seq., Code of Ala. 1975, or these rules.

(ii) Permitting, aiding or abetting the commission of any illegal act in the institution.

(iii) Conduct or practices deemed by the Board to be detrimental to the welfare of the patients in the institution.

2. Conduct and practices deemed detrimental to the welfare of patients of a hospital include:

(i) The administrator of the hospital, the governing authority of a hospital, or an agent authorized by the governing authority of the hospital has deliberately falsified any material information or record submitted as part of the application for licensure or on a Department survey.

(ii) The hospital or its governing authority has changed its corporate name, charter, entity, or its

partnership name or composition to avoid the imposition of liens or court action.

(iii) The governing authority or any principal associated with the governing authority has been found to have engaged in the physical, mental, or sexual abuse or in the financial exploitation of a patient or patients.

(iv) The hospital has been operated in a manner that resulted in one or more violations of applicable laws or other requirements and as a result caused death, injury, disability, or serious risk of death, injury, or disability to any patient or patients of the facility and such conduct causes the Department to reasonably believe that continued licensure of the facility to its current governing authority would likely be detrimental to the life, health, or safety of patients of the hospital.

(v) The hospital is unable to meet its financial obligations and as a result its patients are at risk, as evidenced by more than one utility cut-off notices for non-payment, food vendors or medical supply vendors or both placing the hospital on cash on delivery only status due to non-payment of prior invoices, or the failure of banks to honor employee payroll checks due to insufficient funds on deposit.

(vi) The governing authority or any principal associated with the governing authority has been found to have committed fraud in this or any other jurisdiction.

(vii) The governing authority or any principal associated with the governing authority has falsified records or otherwise made a deliberate and material misrepresentation of facts to an employee of the Department in an attempt to influence the outcome of a survey or some other regulatory compliance determination by the Department.

(viii) The governing authority or any principal associated with the governing authority has induced or attempted to induce a subordinate employee to falsify records or to otherwise make a deliberate and material misrepresentation of facts to an employee of the Department in an attempt to influence the outcome of a survey or some other regulatory compliance determination by the Department.

(ix) The governing authority or any principal associated with the governing authority is operating, or has in the past operated, an unlicensed health care facility.

(x) Other serious misconduct or failure which, in the judgment of the Board, poses a serious risk to patient health or safety.

3. The proposed revocation of a license shall be governed by the provisions of the Alabama Administrative Procedure Act, §41-22-1, et seq., Code of Ala. 1975, 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. A hospital shall be in compliance with 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. A hospital 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 a hospital utilizes the services of a clinical laboratory located outside the State of Alabama, the hospital shall ensure that, in connection with any work performed for the hospital, 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) A hospital shall promptly notify the Department in writing when there is any change in its accrediting organization or deemed status.

Author: W. T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. **Amended:** Filed June 20, 1997; effective July 25, 1997. **Amended:** Filed December 16, 1999; effective January 20, 2000. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012. **Amended:** Filed July 22, 2013; effective August 26, 2013.

420-5-7-.03**Classification Of Hospitals.**

(1) General.

(a) Classification According to Services. Each hospital shall be classified as a General Acute Care Hospital, a Critical Access Hospital or a Specialized Hospital, corresponding to the services offered by the particular institution.

(b) Confinement of Services. A hospital shall confine its services to those designated in the classification, except emergency cases when the life or welfare of the patient is imperiled. In such case the attending physician shall state on the patient record that emergency conditions existed.

(2) General Acute Care Hospitals.

(a) Number of Beds. A General Acute Care Hospital shall have an authorized bed capacity of not fewer than 15 beds for the care and treatment of patients.

(b) Basic Requirements. A General Acute Care Hospital shall provide care for medical and surgical patients, operate a dedicated emergency department, and may not restrict its services to any particular specialty or specialties. Nothing in these rules shall prohibit a hospital from contracting exclusively with one or more specific physician practice groups to provide physician care in a particular specialty or practice area.

(c) A General Acute Care Hospital shall have the following services and facilities available on its campus:

1. A formally organized governing authority with a duly appointed chief executive officer or administrator.
2. A formally organized medical staff which can support the services available at the hospital.
3. A nursing staff under the leadership of a registered professional nurse (RN) who shall report to the hospital's chief executive officer.

4. An adequate staff of professional and technical personnel.
5. Laboratory facilities.
6. Radiology facilities.
7. If surgery is performed, surgical facilities.
8. If obstetrical patients are admitted, obstetrical facilities.
9. A medical records department.
10. A pharmacy.
11. A kitchen for the preparation of patient meals and a dietary department.
12. A maintenance and housekeeping department.
13. Inpatient beds equal to the number of beds in the hospital's authorized bed capacity.
14. A dedicated emergency department. A dedicated emergency department shall include the following: (1) accessibility: shall be operated 24 hours a day/7 days per week; (2) a registered nurse shall be available at all times to the emergency department; (3) an emergency department shall be able to screen patients and if an emergency medical condition is found to exist, provide medical care within the hospital's capacity; and (4) the hospital shall arrange for the provision of emergency medical care beyond the hospital's capacity. The requirement for a dedicated emergency department shall not apply to hospitals operating solely as a Long Term Care Hospital, Rehabilitation Hospital, or Psychiatric Hospital.

(3) Critical Access Hospital.

(a) Basic Requirements. A licensed hospital may apply to become a Critical Access Hospital provided it is first reviewed and approved by the Department's Office of Rural Health. It may provide inpatient care for an average annual length of stay not to exceed 96 hours. It must comply with Alabama's Rural Health Plan and all requirements of these rules applicable to general hospitals.

(b) Number of Beds. A Critical Access Hospital shall have a maximum authorized bed capacity of 45 beds or its licensed bed capacity, whichever is smaller, subject to any additional restrictions imposed by the State Rural Health Plan, Alabama

Certificate of Need requirements, and applicable federal laws and regulations.

(c) A hospital may apply to the Department for designation as a Critical Access Hospital by submitting the necessary forms accompanied by the appropriate fee based on its licensed bed capacity. The certificate of licensure issued by the Department shall contain a notation that the facility has been designated as a Critical Access Hospital.

(d) If the hospital's designation as a Critical Access Hospital is denied, revoked, or rescinded, it shall remain a General Acute Care Hospital. A hospital may voluntarily surrender its status as a Critical Access Hospital at any time by submitting an application to the Department accompanied by the appropriate licensure fee based on its licensed bed capacity. A hospital that has, for any reason, reverted from the status of Critical Access Hospital to the status of General Acute Care Hospital shall no longer be restricted in its length of stay for inpatient care, and may apply for any authorized bed capacity not to exceed its licensed bed capacity.

(4) Specialized Hospitals.

(a) Number of Beds. A Specialized Hospital shall have at least 20 licensed beds.

(b) Basic Requirements. To be classified as a Specialized Hospital, an institution shall provide hospital services to pediatric patients only, pediatric, obstetrical, and gynecological patients only, ophthalmic patients only, psychiatric patients only, long term care patients only, or rehabilitation patients only, and shall have a medical staff and other professional and technical personnel especially qualified in the particular specialty for which the hospital is operated.

(c) Pediatric hospitals; pediatric, obstetrical, and gynecological hospitals; and ophthalmic hospitals shall meet all requirements for General Acute Care Hospitals, except they shall restrict their services offered, patients admitted, and medical privileges to the specialties they serve.

Author: W.T. Geary, Jr., M.D., Carter Sim

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. **Amended:** Filed December 16, 1999; effective January 20, 2000. **Amended:** Filed January 5, 2001; effective February 9, 2001. **Amended:** Filed December 17, 2004; effective January 21, 2005. **Amended:** Filed September 22, 2008; effective October 27, 2008. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.04

The Governing Authority.

(1) A hospital shall have an effective governing authority that is legally responsible for the conduct of the hospital as an institution.

(2) Medical staff. The governing authority shall:

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

(b) Assure that the medical staff has bylaws;

(c) Approve medical staff bylaws and other medical staff rules and regulations;

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

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

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

(3) Chief executive officer. The governing authority shall appoint a chief executive officer who is responsible for managing the hospital.

(4) Care of patients. In accordance with hospital policy, the governing authority shall ensure that the following requirements are met:

(a) Every patient is under the care of:

1. A doctor of medicine or osteopathy (this provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent permitted under applicable state law);

2. A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry in Alabama and who is acting within the scope of his or her license;

3. A doctor of podiatric medicine licensed in Alabama, but only with respect to functions which he or she is legally authorized to perform;

4. A doctor of optometry who is legally authorized to practice optometry in Alabama, and who is acting within the scope of his or her license;

5. A chiropractor who is licensed in Alabama, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist;

6. A clinical psychologist licensed in Alabama, but only with respect to clinical psychologist services; and

7. These rules do not mandate that any particular individual health care practitioner be allowed medical staff membership.

(b) Patients are admitted to the hospital only on the recommendation of a licensed practitioner. If a patient is admitted by a practitioner not specified in this rule, that patient is under the care of a doctor of medicine or osteopathy.

(c) A doctor of medicine or osteopathy is on duty or on call at all times.

(d) A doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that:

1. Is present on admission or develops during hospitalization; and

2. Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is:

(i) Defined by the medical staff;

(ii) Permitted by law; and

(iii) Limited, under this rule, with respect to chiropractors.

(5) Contracted services. The governing authority shall be responsible for services furnished in the hospital 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

hospital 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 hospital shall maintain a list of all contracted services, including the scope and nature of the services provided.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed November 19, 1987; November 21, 1988. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .06 was renumbered to .04 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.05

Patient Rights.

(1) A hospital shall protect and promote each patient's rights.

(2) Notice of rights.

(a) The hospital shall inform each patient, or when appropriate, the patient's representative, of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(b) The hospital shall establish a process for prompt resolution of patient grievances and shall inform each patient whom to contact to file a grievance. The hospital's governing authority shall approve and be responsible for the effective operation of the grievance process and shall review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process shall include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

1. The hospital shall establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

2. The grievance process shall specify time frames for review of the grievance and the provision of a response.

3. In its resolution of the grievance, the hospital shall provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(3) Exercise of rights.

(a) The patient has the right to participate in the development and implementation of his or her plan of care.

(b) The patient or his or her representative has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right shall not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(c) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives.

(d) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(4) Privacy and safety.

(a) The patient has the right to personal privacy.

(b) The patient has the right to receive care in a safe setting.

(c) The patient has the right to be free from all forms of abuse or harassment.

(5) Confidentiality of Patient Records.

(a) The patient has the right to the confidentiality of his or her clinical records.

(b) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital shall not frustrate the legitimate efforts of individuals to gain access to their own medical records and shall actively seek to meet these requests as quickly as its record-keeping system permits.

(6) Restraint or seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and shall be discontinued at the earliest possible time.

(a) Definitions.

1. A restraint is:

(i) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

(ii) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

2. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

3. Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(b) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(c) The type or technique of restraint or seclusion used shall be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(d) The use of restraint or seclusion shall be:

1. In accordance with a written modification to the patient's plan of care; and

2. Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by written hospital policy.

(e) The use of restraint or seclusion shall be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by written hospital policy.

(f) Orders for the use of restraint or seclusion shall never be written as a standing order or on an as needed basis (PRN).

(g) The attending physician shall be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(h) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

1. Four hours for adults 18 years of age or older;

2. Two hours for children and adolescents 9 to 17 years of age; or

3. One hour for children under 9 years of age; and

4. After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy shall see and assess the patient.

(i) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

(j) Restraint or seclusion shall be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(k) The condition of the patient who is restrained or secluded shall be monitored by a physician, other licensed independent practitioner or trained staff that have completed the

training criteria specified in these rules at an interval determined by hospital policy.

(l) Physician and other licensed independent practitioner training requirements shall be specified in hospital policy. Physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy shall have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(m) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient shall be seen face-to-face within one hour after the initiation of the intervention:

1. By a:

(i) Physician or other licensed independent practitioner; or

(ii) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in this rule.

2. To evaluate:

(i) The patient's immediate situation;

(ii) The patient's reaction to the intervention;

(iii) The patient's medical and behavioral condition; and

(iv) The need to continue or terminate the restraint or seclusion.

(n) If the face-to-face evaluation specified in this rule is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant shall consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as soon as possible after the completion of the one-hour face-to-face evaluation.

(o) All requirements specified under this rule are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored:

1. Face-to-face by an assigned, trained staff member; or

2. By trained staff using both video and audio equipment. This monitoring shall be in close proximity to the patient.

(p) When restraint or seclusion is used, there shall be documentation in the patient's medical record of the following:

1. The one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
2. A description of the patient's behavior and the intervention used;
3. Alternatives or other less restrictive interventions attempted (as applicable);
4. The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
5. The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(7) Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

(a) Training intervals. Staff shall be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion:

1. Before performing any of the actions specified in this rule;
2. As part of orientation; and
3. Subsequently on a periodic basis consistent with hospital policy.

(b) Training content. The hospital shall require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

1. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.
2. The use of nonphysical intervention skills.

3. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition.

4. The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

5. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

6. Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the one-hour face-to-face evaluation.

7. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(c) Trainer requirements. Individuals providing staff training shall be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(d) Training documentation. The hospital shall document in the staff personnel records that the training and demonstration of competency were successfully completed.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed November 19, 1987; November 21, 1988. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .06 was renumbered to .04 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.06

Personnel.

(1) Personnel Records. Each hospital shall maintain a personnel record for each employee. As a minimum, the record shall include an application for employment that contains information regarding

the applicant's education, training experience, and if applicable, registration or licensure information.

(2) Each hospital shall establish vaccination requirements for employees that are consistent with current recommendations of the Federal Centers for Disease Control and Prevention (CDC) and the Federal Occupational Safety and Health Administration (OSHA).

(3) Personnel absent from duty because of any communicable disease shall not return to duty until hospital policy on communicable diseases is followed. Said hospital policy shall be consistent with current standards of practice and recommendations of CDC. Documentation of the absence of communicable diseases shall be maintained in facility records.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.07

Physical Environment.

(1) A hospital shall be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(2) Buildings and grounds shall be developed and maintained in such a manner that the safety and well-being of building occupants are assured.

(a) Emergency power and lighting are required in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency power source, battery lamps and flashlights shall be available.

(b) Emergency gas and water supplies are required.

(3) Life Safety from Fire.

(a) A hospital is classified as Health Care Occupancy and shall comply with the codes and standards adopted by the Board. 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.

(b) The hospital shall have procedures for the proper routine storage and prompt disposal of trash.

(c) The hospital shall have written fire control plans containing provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities. Written fire control plans shall also meet the requirements of the currently adopted *Life Safety Code* for fire drills, evacuation and relocation, and procedures during fire emergencies. Fires shall be reported to the Department's Technical Services Unit within 24 hours of the occurrence.

(d) The hospital shall maintain written evidence of regular inspection and approval by state or local fire control agencies.

(e) Roller latches are prohibited on doors separating corridors from adjacent spaces.

(f) Emergency lighting shall provide illumination in accordance with the currently adopted *Life Safety Code* for at least 90 minutes.

(g) Alcohol-based hand rub dispensers shall be installed in a manner that:

1. Minimizes leaks and spills.
2. Adequately protects against inappropriate access.
3. Complies with the requirements of the *Life Safety Code*.

(4) Facilities. The hospital shall maintain adequate facilities for its services.

(a) Diagnostic and therapeutic facilities shall be located for the safety of patients.

(b) Facilities, supplies, and equipment shall be maintained to ensure an acceptable level of safety and quality.

(c) The extent and complexity of facilities shall be determined by the services offered.

(d) There shall be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

(5) Submission of Plans and Specifications.

(a) New Facilities, Additions, and Alterations. 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. This is required for any building that is intended to contain a hospital, and for additions and alterations to existing facilities.

(b) 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 beds over those for which the facility is licensed, need not be submitted for approval.

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

(7) 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: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed August 22, 1990. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. **Amended:** Filed February 20, 1997; effective March 27, 1997. **Amended:** Filed December 16, 1999; effective January 20, 2000. **Amended:** Filed June 18, 2002; effective July 23, 2002. **Amended:** Filed June 23, 2004; effective July 28, 2004.

Repealed and New Rule: Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .05 was renumbered to .07 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.08

Patient Transport.

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 emergency medical services 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 ambulance service operators licensed by the Board. 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 ambulance service operator in that state. For the purposes of this rule, an upright position means no more than 20 degrees from vertical.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed June 23, 2004; effective July 28, 2004.

Repealed and New Rule: Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .29 was renumbered to .08 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.09

Medical Staff.

(1) The hospital shall have an organized medical staff that operates under bylaws approved by the governing authority and is responsible for the quality of medical care provided to patients by the hospital.

(2) Composition of the medical staff. The medical staff shall be composed of doctors of medicine or osteopathy and may also be composed of other practitioners appointed by the governing authority.

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

(b) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing authority on the appointment of the candidates.

(c) Hospitals may provide telemedicine services to their patients if these medical services are provided pursuant to a written contract. If these services are provided by contract with another hospital that hospital shall be a Medicare-participating hospital and assure the physicians providing the telemedicine services are privileged to offer the services in the second hospital and are licensed in Alabama. If these services are provided by a distant-site telemedicine entity other than a Medicare-participating hospital, the physicians must be appropriately credentialed to provide these services and must be licensed in Alabama.

(3) Medical staff organization and accountability. The medical staff shall be well organized and accountable to the governing authority for the quality of the medical care provided to patients.

(a) The medical staff shall be organized in a manner approved by the governing authority.

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

(c) The responsibility for organization and conduct of the medical staff shall be assigned only to an individual doctor of medicine or osteopathy.

(4) Medical staff bylaws. The medical staff shall adopt and enforce bylaws to carry out its responsibilities. The bylaws shall:

(a) Be approved by the governing authority;

(b) Include a statement of the duties and privileges of each category of medical staff (such as active or courtesy);

(c) Describe the organization of the medical staff;

(d) 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 authority;

(e) Include a requirement that:

1. A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination shall be completed and documented by a physician, an oromaxillofacial surgeon, or other qualified licensed individual in accordance with hospital policy.

2. An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, shall be completed and documented by a physician, an oromaxillofacial surgeon, or other qualified licensed individual in accordance with hospital policy.

(f) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(5) Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and deaths of medical-

legal and educational interest. The mechanism for documenting permission to perform an autopsy shall be defined. There shall be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .08 was renumbered to .09 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.10

Quality Assurance Or Quality Assessment And Performance Improvement (QAPI).

(1) The hospital shall develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assurance or quality assessment and performance improvement (QAPI) program. The hospital's governing authority shall ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital shall maintain and demonstrate evidence of its QAPI program for review by the Department.

(2) Program scope.

(a) The program shall include an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(b) The hospital shall measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(3) Program data.

(a) The program shall incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization (QIO).

(b) The hospital shall use the data collected to:

1. Monitor the effectiveness and safety of services and quality of care; and
2. Identify opportunities for improvement and changes that will lead to improvement.

(c) The frequency and detail of data collection shall be specified by the hospital's governing authority.

(4) Program activities.

(a) The hospital shall set priorities for its performance improvement activities that:

1. Focus on high-risk, high-volume, or problem-prone areas;
2. Consider the incidence, prevalence, and severity of problems in those areas; and
3. Affect health outcomes, patient safety, and quality of care.

(b) Performance improvement and quality assurance activities shall track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(c) The hospital shall take actions aimed at performance improvement and, after implementing those actions, the hospital shall measure its success, and track performance to ensure that improvements are sustained.

(5) Performance improvement projects. As part of its QAPI program, the hospital shall conduct performance improvement projects.

(a) The number and scope of distinct improvement projects conducted annually shall be proportional to the scope and complexity of the hospital's services and operations.

(b) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(c) The hospital shall document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(d) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(6) Executive responsibilities. The hospital's governing authority (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(a) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(b) That the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(c) That clear expectations for safety are established.

(d) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(e) That the determination of the number of distinct improvement projects is conducted annually.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Repealed and New Rule: Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .07 was renumbered to .10 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.11

Nursing Services.

(1) The hospital shall have an organized nursing service that provides 24-hour nursing services. The nursing services shall be furnished or supervised by a registered nurse.

(2) Organization. The hospital shall have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service shall be a licensed registered nurse with an active, unencumbered registered nurse license issued by the Alabama Board of Nursing. He or she 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.

(3) Staffing and delivery of care. The nursing service shall have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There shall 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. Where there is a question about a physician's order the physician may be contacted by nursing staff.

(a) The hospital shall provide 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 nursing service shall have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(c) A registered nurse shall supervise and evaluate the nursing care for each patient.

(d) The hospital shall ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(e) A registered nurse shall 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.

(f) Non-employee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The director of nursing service shall provide for the adequate supervision, licensure verification, and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(4) Preparation and administration of drugs. Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the practitioner or practitioners responsible for the patient's care, and accepted standards of practice.

(a) All drugs and biologicals shall be administered by, or under 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.

(b) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of

contraindications, orders for drugs and biologicals shall be documented and signed by a practitioner who is authorized to write orders by hospital policy, and who is responsible for the care of the patient.

1. If verbal orders are used, they are to be used infrequently.

2. When verbal orders are used, they shall only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with federal and state law.

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

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

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed May 23, 1986.

Repealed and New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012. **Amended:** Filed July 22, 2013; effective August 26, 2013.

Ed. Note: Rule .09 was renumbered to .11 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.12

Infection Control.

(1) The hospital 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.

(2) Organization and policies. A person or persons shall be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The infection control officer or officers shall develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(3) Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing services shall:

- (a) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and
 - (b) Be responsible for the implementation of successful corrective action plans in affected problem areas.
- (4) Laundry services provided by the hospital shall have reasonable and adequate infection control practices used at all times.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New**

Rule: Filed August 24, 2012; effective September 28, 2012.

Amended: Filed July 22, 2013; effective August 26, 2013.

Ed. Note: Rule .16 was renumbered to .12 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.13

Medical Record Services.

- (1) The hospital shall have a medical record service that has administrative responsibility for medical records. A medical record shall be maintained for every individual evaluated or treated in the hospital.
- (2) Organization and staffing. The organization of the medical record service shall be appropriate to the scope and complexity of the services performed. The hospital shall employ adequate personnel to ensure prompt completion, filing, and retrieval of records.
- (3) Form and retention of record. The hospital shall maintain a medical record for each inpatient and outpatient. Medical records shall be accurately written, promptly completed, properly filed and retained, and accessible. The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.
- (a) Medical records shall be retained in their original or legally reproduced form for a period of at least five years. In the case of minor patients, records shall be retained for at least five years after the patient has reached the age of majority.
 - (b) The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval

by diagnosis and procedure, in order to support medical care evaluation studies.

(c) The hospital shall 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 shall ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records shall be released by the hospital only in accordance with federal or state laws, court orders, or subpoenas.

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

(a) All patient medical record entries shall be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

1. All orders, including verbal orders, shall be dated, timed, and authenticated promptly by the ordering practitioner, except as noted below.

2. All orders, including verbal orders, shall be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy.

3. All verbal orders must be authenticated within such time period as provided by hospital policy, but no more than 30 days following entry of the order.

(b) All records shall document the following, as appropriate:

1. Evidence of:

(i) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination shall be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(ii) An updated examination of the patient, including any changes in the patient's condition, when the

medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination shall be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

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 the medical staff.
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 provisions for follow-up care.
8. Final diagnosis with completion of medical records within 30 days following discharge.

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

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. **Amended:** Filed January 19, 1996; effective February 23, 1996. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

Amended: Filed July 22, 2013; effective August 26, 2013.

Ed. Note: Rule .10 was renumbered to .13 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.14

Food Dietetic Services.

(1) The hospital shall have organized dietary services that are directed and staffed by adequate qualified personnel. 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) Organization.

(a) The hospital shall have a full-time employee who:

1. Serves as director of the food and dietetic service;
2. Is responsible for the daily management of the dietary services; and
3. Is qualified by experience or training.

(b) There shall be a qualified dietitian, full-time, part-time, or on a consultant basis.

(c) There shall be administrative and technical personnel competent in their respective duties.

(3) Diets. Menus shall meet the needs of the patients.

(a) Therapeutic diets shall be prescribed by the practitioner or practitioners responsible for the care of the patients or by a dietitian licensed by the Alabama Board of Examiners for Dietetics and Nutritionists as authorized by the medical staff.

(b) Nutritional needs shall be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients or by a dietician licensed by the Alabama Board of Examiners for Dietetics and Nutritionists as authorized by the medical staff.

(c) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel.

Author: W.T. Geary, Jr., M.D., Carter Sims, Dana Billingsley

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New Rule:** Filed August 24, 2012; effective September 28, 2012.

Amended: Published March 31, 2022; effective May 14, 2022.

420-5-7-.15**Emergency Services.**

(1) The hospital shall meet the emergency needs of patients in accordance with acceptable standards of practice.

(2) Organization and direction.

(a) The services shall be organized under the direction of a qualified member of the medical staff.

(b) The services shall be integrated with other departments of the hospital.

(c) The policies and procedures governing medical care provided in the emergency service or department shall be established by, and are a continuing responsibility of, the medical staff.

(3) Personnel.

(a) The emergency services shall be supervised by a qualified member of the medical staff.

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

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: **New Rule:** Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .21 was renumbered to .15 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.16**Pharmaceutical Services.**

(1) The hospital shall have pharmaceutical services that meet the needs of the patients. The institution shall have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff in conjunction with

pharmacy department is responsible for developing and approving policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(2) Pharmacy management and administration. The pharmacy or drug storage area shall be administered in accordance with accepted professional principles.

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

(b) The pharmaceutical service shall have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

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

(3) Delivery of services. In order to provide patient safety, drugs and biologicals shall be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state law.

(a) All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with state and federal laws.

(b) All drugs and biologicals shall be kept in a secure area, and locked when appropriate.

(c) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be kept locked within a secure area.

(d) Only authorized personnel may have access to locked areas.

(e) Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use.

(f) When a pharmacist is not available, drugs and biologicals shall be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state law.

(g) Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the medical staff.

(h) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(i) Abuses and losses of controlled substances shall be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(j) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

(k) A formulary system shall be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed May 20, 1992.

Repealed and New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .11 was renumbered to .16 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.17

Surgical Services.

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

(2) Organization and staffing. The organization of the surgical services shall be appropriate to the scope of the services offered.

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

(b) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" or "scrub techs" under the supervision of a registered nurse.

(c) Qualified registered nurses may perform circulating duties in the operating room. In accordance with state laws and

approved medical staff policies and procedures, LPNs may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies. Registered nurses may also serve as registered nurse first assistants (RNFAs).

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

(3) Delivery of service. Surgical services shall be consistent with needs and resources. Policies governing surgical care shall be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(a) Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

1. A medical history and physical examination shall be completed and documented no more than 30 days before or 24 hours after admission or registration.

2. An updated examination of the patient, including any changes in the patient's condition, shall be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

(b) A properly executed informed consent form for the operation shall be in the patient's chart before surgery, except in emergencies.

(c) The following equipment shall be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(d) There shall be adequate provisions for immediate post-operative care.

(e) The operating room register shall be complete and up-to-date.

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

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: filed September 1, 1982. **Amended:** Filed March 20, 1992.

Repealed and New Rule: Filed November 18, 1994; effective

December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.18

Anesthesia Services.

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

(2) Organization and staffing. The organization of anesthesia services shall be appropriate to the scope of the services offered. Anesthesia must be administered only by:

(a) An anesthesiologist;

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

(c) A dentist or oral surgeon;

(d) A podiatrist, but limited to administering local anesthetics to the foot;

(e) A certified registered nurse anesthetist (CRNA) who is performing or assisting in any act involving the determination, preparation, administration, or monitoring of any drug used to render an individual insensible to pain for surgical or other therapeutic or diagnostic procedures and who is under the direction of a physician licensed to practice medicine, or a dentist, who is immediately available; or

(f) An anesthesiologist's assistant who is under the direction of an anesthesiologist who is immediately available.

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

(a) A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

(b) An intra-operative anesthesia record.

(c) A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, no later than 48 hours after surgery or a procedure requiring

anesthesia services. The post-anesthesia evaluation for anesthesia recovery shall be completed in accordance with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New**

Rule: Filed August 24, 2012; effective September 28, 2012.

420-5-7-.19

Radiologic Services.

(1) The hospital shall maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications.

(2) Radiologic services. The hospital shall maintain, or have available, radiologic services according to needs of the patients.

(3) Safety for patients and personnel. The radiologic services, particularly ionizing radiology procedures, shall be free from hazards for patients and personnel.

(a) Proper safety precautions shall be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(b) Periodic inspection of equipment shall be made and hazards identified must be promptly corrected.

(c) Radiation workers shall be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

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

(4) Personnel.

(a) A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret only those radiologic tests that are determined by the medical staff to require a radiologist's

specialized knowledge. For purposes of this rule, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(b) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(5) Records. Records of radiologic services shall be maintained.

(a) The radiologist or other practitioner who performs radiology services shall sign reports of his or her interpretations.

(b) The hospital shall maintain the following for at least five years:

1. Copies of reports and printouts.
2. Films, scans, and other image records, as appropriate.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** Filed May 20, 1992.

Repealed and New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .12 was renumbered to .19 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.20

Laboratory Services.

(1) The hospital shall maintain, or have available, adequate laboratory services to meet the needs of its patients.

(2) Adequacy of laboratory services. The hospital shall have laboratory services available, either directly or through a contractual agreement with a certified laboratory.

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

(b) A written description of services provided shall be available to the medical staff.

(c) The laboratory shall make provision for proper receipt and reporting of tissue specimens.

(d) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(3) The hospital's laboratory shall have a current federal CLIA number.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New**

Rule: Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .13 was renumbered to .20 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.21

Nuclear Medicine Services.

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

(2) Organization and staffing. The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

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

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

(3) Delivery of service. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

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

(b) There is proper storage and disposal of radioactive material.

(c) If laboratory tests are performed in the nuclear medicine service, the service shall meet the applicable requirement for laboratory services.

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

- (a) Maintained in safe operating condition; and
- (b) Inspected, tested, and calibrated at least annually by qualified personnel.

(5) Records. The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

- (a) The hospital shall maintain copies of nuclear medicine reports for at least 5 years.
- (b) The practitioner approved by the medical staff to interpret diagnostic procedures shall sign and date the interpretation of these tests.
- (c) The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals.
- (d) Nuclear medicine services shall be ordered only by a practitioner whose scope of federal or state licensure and whose defined staff privileges allow such referrals.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. Repealed and **New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rule .19 was renumbered to .21 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.22

Rehabilitation Services.

(1) If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services shall be organized and staffed to ensure the health and safety of patients.

(2) Organization and staffing. The organization of the service shall be appropriate to the scope of the services offered.

- (a) The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(b) Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, shall be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists.

(3) Delivery of services. Services shall only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures. All rehabilitation services orders shall be documented in the patient's medical record. The provision of care and the personnel qualifications shall be in accordance with national acceptable standards of practice.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.23

Respiratory Care Services.

(1) The hospital shall meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(2) Organization and Staffing. The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

(a) There shall be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

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

(3) Delivery of Services. Services shall be delivered in accordance with medical staff directives.

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

(b) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit shall meet the applicable requirements for laboratory services.

(c) Services shall only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope or practice, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures.

(d) All respiratory care services orders shall be documented in the patient's medical record.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.24

Outpatient Services.

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

(2) Organization. Outpatient services shall be appropriately organized and integrated with inpatient services.

(3) Personnel. The hospital shall:

(a) Assign one or more individuals to be responsible for outpatient services; and

(b) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012. **Amended:** Filed July 22, 2013; effective August 26, 2013.

Ed. Note: Rule .20 was renumbered to .24 as per certification filed August 24, 2012; effective September 28, 2012.

420-5-7-.25

Discharge Planning.

(1) The hospital shall have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures shall be specified in writing.

(2) Identification of patients in need of discharge planning. The hospital shall identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(3) Discharge planning evaluation.

(a) The hospital shall provide a discharge planning evaluation to the patients identified in paragraph (2) of this rule, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(b) A registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, the evaluation.

(c) The discharge planning evaluation shall include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.

(d) The discharge planning evaluation shall include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(e) Hospital personnel shall complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(f) The hospital shall include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and shall discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(4) Discharge plan.

(a) A registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(b) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital shall develop a discharge plan for the patient.

(c) The hospital shall arrange for the initial implementation of the patient's discharge plan.

(d) The hospital shall reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

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

(5) Transfer or referral. The hospital shall transfer or refer patients, along with necessary medical information, to appropriate licensed facilities, agencies, or outpatient services, as needed, for follow up or ancillary care. In no event shall the hospital knowingly transfer or refer a patient to an unlicensed health care facility in violation of § 22-21-33(b), Code of Ala. 1975.

(6) Reassessment. The hospital shall reassess its discharge planning process on an on-going basis. The reassessment shall include a review of discharge plans to ensure that they are responsive to discharge needs.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.26

Psychiatric Hospitals.

(1) A psychiatric hospital, or an inpatient psychiatric program within a hospital that is not a psychiatric hospital, shall be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons.

(2) Special medical record requirements.

(a) The medical records maintained by a psychiatric hospital shall permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(b) Development of assessment and diagnostic data. Medical records shall stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

1. The identification data shall include the circumstances under which the patient was admitted and/or is being treated - i.e., voluntary, involuntary, committed by court, evaluation and recertification.

2. A provisional or admitting diagnosis shall be made on every patient at the time of admission, and shall include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

3. The reasons for admission shall be clearly documented as stated by the patient and/or others significantly involved.

4. The social service records, including reports of interviews with patients, family members, and others, shall provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

5. When indicated, a complete neurological examination shall be recorded at the time of the admission physical examination.

(c) Psychiatric evaluation. Each patient shall receive a psychiatric evaluation that shall:

1. Be completed within 60 hours of admission;

2. Include a medical history;

3. Contain a record of mental status;

4. Note the onset of illness and the circumstances leading to admission;

5. Describe attitudes and behavior;

6. Estimate intellectual functioning, memory functioning, and orientation; and

7. Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(d) Treatment plan.

1. Each patient shall have an individual comprehensive treatment plan that shall be based on an inventory of the patient's strengths and disabilities.

(i) The written plan shall include:

(I) A substantiated diagnosis;

(II) Short-term and long-range goals;

(III) The specific treatment modalities utilized;

(IV) The responsibilities of each member of the treatment team; and

(V) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(ii) The treatment received by the patient shall be documented in such a way to assure that all active therapeutic efforts are included.

(e) Recording progress. Progress notes shall be recorded by the doctor of medicine or osteopathy responsible for the care of the patient, nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but shall be recorded at least weekly for the first two months and at least once a month thereafter and shall contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(f) Discharge planning and discharge summary. The record of each patient who has been discharged shall have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

(3) Special staff requirements.

(a) The hospital shall have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(b) Personnel. The hospital shall employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

1. Evaluate patients;
2. Formulate written individualized, comprehensive treatment plans;
3. Provide active treatment measures; and
4. Engage in discharge planning.

(c) Director of inpatient psychiatric services; medical staff. Inpatient psychiatric services shall be under the supervision of a clinical director, service chief, or equivalent, which is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy shall be adequate to provide essential psychiatric services.

1. The clinical director, service chief, or equivalent, shall meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.
2. The director shall monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(d) Availability of medical personnel. Doctors of medicine or osteopathy and other appropriate professional personnel shall be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution shall have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement shall be established for transferring patients to a General Acute Care Hospital.

(e) Nursing services. The hospital shall have a qualified director of psychiatric nursing services. In addition to the director of nursing, there shall be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

1. The director of psychiatric nursing services shall be a registered nurse with an active, unencumbered Alabama license who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the Commission on Collegiate Nursing Education, the National League for Nursing, or be qualified by education and experience in the care of

the mentally ill. The director shall demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

2. The staffing pattern shall insure the availability of a registered professional nurse 24 hours each day. There shall be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(f) Psychological services. The hospital shall provide or have available psychological services to meet the needs of the patients.

(g) Social services. There shall be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services shall be furnished in accordance with accepted standards of practice and established policies and procedures.

1. The director of the social work department or service shall have a master's degree from an accredited school of social work or shall be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member shall have this qualification.

2. Social service staff responsibilities shall include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(h) Therapeutic activities. The hospital shall provide a therapeutic activities program.

1. The program shall be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

2. The number of qualified therapists, support personnel, and consultants shall be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.27

Emergency Preparedness.

(1) The hospital shall develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The hospital shall participate in the Alabama Incident Management System (AIMS) and coordinate with federal, state, and local emergency preparedness and health authorities to identify likely risks for its area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and well being of patients.

(2) The following issues should be considered when developing the comprehensive emergency plans(s):

(a) The differing needs of each location where the hospital operates;

(b) The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);

(c) Security of patients and walk-in patients;

(d) Security of supplies from misappropriation;

(e) Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;

(f) Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);

(g) Communication among staff within the hospital itself;

(h) Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;

(i) Identification, availability and notification of personnel that are needed to implement and carry out the hospital's emergency plans;

(j) Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;

(k) Provisions if gas, water, electricity supply is shut off to the community;

(l) Transfer or discharge of patients to home, other healthcare settings, or other hospitals;

(m) Transfer of patients with hospital equipment to another hospital or healthcare setting; and

(n) Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

(3) The hospital shall work cooperatively with federal, state and local emergency preparedness agencies and officials in order to identify likely risks to the community (e.g., natural disasters, mass casualties, terrorist acts, etc.) to anticipate demands and resources needed by the hospital emergency services, and to develop plans, methods and coordinating networks to address those anticipated needs.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.

Ed. Note: Rules 420-5-7-.28, Obstetrics And Newborn and 420-5-7-.15, Utilization Review were repealed as precertification filed August 24, 2012; effective September 28, 2012. See history below:

420-5-7-.28

Obstetrics And Newborn (Repealed).

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 18, 1994; effective December 23, 1994. **Repealed:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-.15 (Repealed)

Utilization Review (Repealed).

The document entitled 42 Code of Federal Regulations, (42 C.F.R.) "Public Health" part 482.30 as revised as of October 1, 1992, is hereby incorporated by reference and made a part of this rule as if set out in full and all provisions thereof on November 16, 1994. Copies of the adopted

reference can be obtained from the United States Government Printing Office, Washington, D.C. 20402-9328.

Author: L. O'Neal Green

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Repealed and New Rule:** Filed November 18, 1994; effective December 23, 1994. **Repealed:** Filed August 24, 2012; effective September 28, 2012.

420-5-7-A**Appendix A Information On The Application Process for Hospitals.**

Applications must be submitted as a paper copy. All forms and instructions are available on the Alabama Department of Public Health web site at <http://www.adph.org>.

The application information is under the heading "Health Care Facilities," which is found in the blue banner on the left hand side of the home page.

Applications must be submitted to:

STATE OF ALABAMA**DEPARTMENT OF PUBLIC HEALTH - DIVISION OF PROVIDER SERVICES****P. O. BOX 303017****MONTGOMERY, ALABAMA 36130**

Questions regarding licensure can be directed to the Division of Provider Services at 334-206-5175.

Author: W.T. Geary, Jr., M.D., Carter Sims

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: **Repealed and New Rule:** Filed August 24, 2012; effective September 28, 2012.