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

CHAPTER 420-5-2
AMBULATORY SURGICAL TREATMENT FACILITIES

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420-5-2-.01 General.

(1) Legal Authority for Adoption of Rules. Under and by virtue of authority vested in it by the Legislature of Alabama (Code of Ala. 1975, §§22-21-20, et seq.), the State Committee of Public Health does hereby adopt and promulgate the following rules governing outpatient surgical treatment centers licensed to operate in the State of Alabama.

(2) Definitions (a list of selected terms often used in connection with these Rules):

(a) AAC Rule means Alabama Administrative Code Rule.

(b) Administrator means a natural person who is the governing authority of a health care facility or a natural person who is designated by the governing authority of a health care facility. Such person must have sufficient authority to interpret and implement all policies of the owner or proprietor, and must be sufficiently qualified to perform those tasks. Such person shall be the addressee of all correspondence and inquiries from the State Committee of Public Health.

(c) Advisory Board. See Section 22-21-27 of Appendix.

(d) Ambulatory Surgical Center means any health care facility with the primary purpose of providing medically necessary or elective surgical care. Excluded from this definition are the offices of private physicians and dentists, including those organized as professional corporations, professional associations, partnerships, or sole proprietorships. Also excluded from this definition are health care facilities defined as hospitals under section (i), below.

(e) "Specialized Ambulatory Surgical Center" means an ambulatory surgical center that provides surgical services in an exclusive specialty, such as orthopedics, pediatrics, gynecology and obstetrics, ophthalmology, or other specialized practice.

(f) Health Care Facility means any structure, building, office, or portion thereof where medical procedures are performed.

(g) Board or State Board of Health means the State Committee of Public Health.

(h) Facilities for Surgical Treatment of Patients Not Requiring Hospitalization as referred to in these rules means "Ambulatory Surgical Centers."

(i) Governing Authority means the owner or proprietor of health care facility, or the body, such as a board of directors, which exercises control over a health care facility on behalf of its owner or proprietor.

(j) Hospital means a health care facility duly licensed by the State Committee of Public Health under Chapter 420-5-7, Alabama Administrative Code, to offer to the public not less than 15 beds and other facilities for use in diagnosis and treatment of persons in need of acute care for illness, disease, injury, deformity, infirmity, abnormality or pregnancy. A health care facility meets this definition only if the facility is licensed to offer and actually does offer such care or service for not less than 24 consecutive hours in any week to two or more individuals not related by blood or marriage to the owner and/or administrator of the facility.

(k) Medical Director (Qualified) means the physician responsible for planning, organizing, conducting, and directing the medical affairs of the ambulatory surgical center. The Physician-Director must meet either of the following requirements to be considered qualified:

1. Is Board Eligible or Board Certified in surgery or anesthesia and has had at least 12 months of experience or training in the care of patients in a surgical environment; or

2. During the 5 year period prior to the effective date of these rules, has served for at least 12 months as director of a surgical unit.

However, in those areas where a qualified medical Director is not available to direct an ambulatory surgical center, another physician may direct the

facility, subject to the approval of the State Committee of Public Health.

(l) Medical Staff means currently licensed physicians and dentists and podiatrists who are privileged by agreement with licensee to attend patients within the institution.

(m) Patient means a person admitted to the ambulatory surgical center by and upon the recommendation of a physician and who is to receive the medical care recommended by the physician.

(n) Pharmacy means a place licensed by the Alabama State Board of Pharmacy in which prescriptions, drugs, medicines, chemicals, and poisons are sold, offered for sale, compounded or dispensed, and shall include all places whose title may imply the sale, offering for sale, compounding or dispensing of prescriptions, drugs, medicines, chemicals, or poisons.

(o) Pharmacist means a person currently licensed to practice pharmacy in Alabama under the provisions contained in current state statutes.

(p) Physician means a person currently licensed by the Medical Licensure Commission, State of Alabama, to practice medicine and surgery.

(q) Podiatrist means a person currently licensed to practice podiatry in Alabama under the provisions of current state statutes.

(r) Registered Nurse (RN) means a person who holds an active registered nurse license issued by the Alabama Board of Nursing or a multistate registered nurse license issued by another Nurse Licensure Compact party state.

(s) Licensed Practical Nurse (LPN) means a person currently licensed in the State of Alabama in accordance with Code of Ala. 1975, §§34-21-1, et seq.

(t) These Rules means Rules 420-5-2-01 through 420-5-2-.04, Chapter 420-5-2, Ambulatory Surgical Treatment Facilities, Alabama Administrative Code.

(3) Type of License.

(a) Regular License. A regular license may be issued by the State Committee of Public Health after the Committee has determined that the outpatient surgical treatment center is in substantial compliance with the rules herein adopted.

(b) Temporary License.

1. At its discretion, the State Board of Health may issue a license which indicates a temporary condition of non-compliance with these rules. A temporary license may be issued when the Committee is satisfied that preparations are being made to qualify for a regular license or as provided below, and that notwithstanding the deficiencies, appropriate measures have been taken to minimize any threat to the health and safety of patients and personnel. A temporary license may be granted for a calendar year, but not to exceed five (5) successive 1 year terms.

An ambulatory surgical center may be issued a temporary license prior to opening if in compliance with the provisions of these rules relative to the physical plant and staffing. The license issued under AAC Rule 420-5-2-.01(3)(b) shall be valid until the issuance of a regular license or December 31 of the year in which the license was issued unless suspended or revoked prior to that date. A temporary license may be reissued under AAC Rule 420-5-2-.01(3)(b) when it has been demonstrated to the Board that specific efforts are being made to comply with these rules.

2. An ambulatory surgical center which is in existence on the effective date of these rules may be issued a temporary license under one or more of the following conditions:

(i) Where failure to qualify for a regular license is due to the requirements as herein required.

(ii) Where the governing authority is making specific plans to establish an ambulatory surgical center which meets the rules or is actually in the process of meeting these rules.

(iii) Where a formal appeal of an administrative decision is pending action by the State Committee of Public Health.

(c) Probational License. At its discretion, the State Board of Health may issue a probational license under one or more of the following conditions, and then only when the Board is satisfied, notwithstanding its deficiencies, appropriate measures have been taken to minimize any threat to the health and safety of patients and personnel. A probational license may be granted for a calendar 1 year not to exceed two successive one-year terms:

1. When the Committee has reason to believe the operation is questionable.

2. When the Committee has reason to believe the facility is not making specific plans to comply with these rules or the ambulatory surgical center's ability to comply is questionable.

3. Conduct or practices not deemed by the Committee to be in the patients' best interest, e.g., the owner(s), physicians, or employee(s) are determined to be unethical, have committed fraud or abuse, or have been found to be aiding or abetting the commission of an illegal act.

(4) Licensing.

(a) Application for License. All ambulatory surgical centers shall apply for licensure on a form designated by the State Committee of Public Health. The application will reflect all data required by Code of Ala. 1975, §§22-21-20, et seq., a copy of which is contained in Appendix.

(b) Fee. See Section 22-21-24 of Appendix.

(c) Name of Facility. Every ambulatory surgical center shall be designated by a permanent and distinctive name which shall not be changed until an application has been completed and approved. Words in the name of the center that may reflect a different type of facility or service shall not be used.

(d) Separate License. When more than one facility is operated under the same operating entity, a separate license shall be required for each facility. Separate licenses are not required for separate buildings on the same ground used by the same facility.

(e) Reissuance of License.

1. The following changes in the status of the facility will require issuance of a new license, upon application and payment of licensure fee (if applicable) as required by current statutes:

(i) Change in facility ownership or operating entity (fee required).

(ii) Change in name (no fee required).

(iii) Change of locality (no fee required).

2. The governing authority shall file with the State Committee of Public Health, an application for license 30 days before any proposed change requiring a new license, in order to permit processing of the application and

issuance of the license on the desired effective date of the change.

(f) Specialized Ambulatory Surgical Center. Ambulatory surgical centers that limit their practice to a particular medical specialty may apply for licensure as a specialized ambulatory surgical center. A specialized ambulatory surgical center shall have a medical staff and other professional and technical personnel qualified to provide surgical treatment and services in the specialty area. A facility licensed as a specialized ambulatory surgical center must limit its surgical practice to its designated medical specialty. A specialized ambulatory surgical center is required to meet all other requirements of these rules for ambulatory surgical centers.

(5) Right of Appeal.

(a) Review of Licensure Inspection Reports and Statement of Deficiencies. In cases of errors or differences of opinions as to interpretations and/or applicability of these rules, the licensee may request orally or in writing a review of such points of difference. Opportunity for prompt review shall be afforded by the Alabama Department of Public Health and, where applicable, letters of clarification sent to the licensee.

(b) Administrative Decisions.

1. The Licensure Advisory Board will provide an opportunity for a fair hearing to every licensee who is dissatisfied with administrative decisions made in the application of these rules.

2. The licensee shall present his complaint in writing, within 30 days, and may, at his discretion, be present during the hearing, and/or be represented by legal counsel.

3. The licensee may present such evidence as may be deemed necessary and pertinent to his request.

4. Upon completion of the hearing, the Licensure Advisory Board shall present its findings, conclusions, and recommendations to the State Committee of Public Health for final action.

(c) Decisions Made by State Committee of Public Health. Decisions rendered by the State Committee of Public Health in respect to licensure status or amendments to these rules shall be final and binding.

(6) Exceptions.

(a) Research Projects Application for Waiver. Any licensee who is or contemplates being engaged in a bona fide research program which may be in conflict with one or more specific provisions of these rules may make application for waiver of the specific provisions in conflict. Application for waiver shall be made in writing to the Licensure Advisory Board who shall, upon completion of its investigation, send its findings, conclusions and recommendations to the State Committee of Public Health for final action.

(b) Exceptions to Regulations. At its discretion, the State Committee of Public Health may grant an exception to, or modify the application of, one or more provisions of these rules or reference codes for a period and under conditions, if any, determined by the Committee. The exceptions or modifications shall be based on hardship, impracticality, or economic infeasibility in complying with the rules. The center's request shall be in writing, shall state the specific provisions for which the exception or modification is requested, and reason for each requested exception or modification.

(c) Disclosure of Information. Information received through on-site inspections may be disclosed to any interested party upon written request. Information received through means other than inspections shall not be publicly disclosed.

Author: L. O'Neal Green
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420-5-2-.02 Administration.

(1) Governing Authority.

(a) Responsibility. The governing authority or the owner or the person or persons designated by the owner as the governing authority shall be the supreme authority of the facility, responsible for the management, control, and operation of the facility, including the appointment of a qualified medical director.

(b) Organization. The governing authority shall be formally organized in accordance with a written constitution and/or bylaws. In the event the governing authority consists of one person, this requirement must still be met. Such constitution and/or bylaws shall include:

1. Identification of the facility.

2. The purpose for which the facility is organized.

3. Length of tenure and mechanism for appointment of members of the governing body.

4. Appointment and duties of the chief executive officer.

5. Requirement that the medical staff be organized in accordance with bylaws approved by the governing authority.

6. Mechanism for appointment and reappointment at regular intervals of the medical staff members and the medical director in accordance with written bylaws.

7. Mechanism for approval of bylaws or policies governing the activities of the medical director and medical staff.

(c) Meetings. The governing authority shall meet regularly. A copy of the minutes of these meetings shall be kept as a permanent record of the facility.

(d) Notification of Chief Executive Officer. The State Board of Health shall be advised of the chief executive officer's name within 15 days of his appointment.

(2) The Chief Executive Officer.

(a) Responsibility. There shall be a competent, well trained chief executive officer who shall assume authority and responsibility for directing, coordinating, and supervising the overall activities of the facility. The chief executive officer and the medical director or other qualified employee of the facility may be one and the same person depending upon the size and degree of management and supervision required for appropriate operation of the facility.

(b) Enforcement of Medical Staff Regulations. As the authorized representative of the governing authority, the chief executive officer shall have the authority to enforce medical staff rules and regulations with regard to patient care, after consultation with appropriate members of the medical staff.

(c) Policies and Procedures. The chief executive officer shall be responsible for assuring either directly or through delegation of authority, that policies promulgated by the governing authority are carried out. Appropriate procedures to enforce these policies, assure proper patient care and

safety, and meet requirements of these rules shall be developed in writing by an appropriate committee composed of professionals and shall be reviewed at least annually.

(d) Consultation. The center shall seek consultation where necessary for the improvement of efficiency of operation and the quality of patient care.

(3) Personnel.

(a) Medical Director. A qualified physician medical director shall be appointed or designated by the governing body. It shall be the responsibility of the medical director to:

1. Develop or advise appropriate personnel of the center in the development of medical procedures governing operation of the facility.

2. Either perform or assure proper performance by other physicians of medical procedures carried out in the center.

3. Periodically, at least annually, participate in a review for appropriateness of techniques and procedures relating to operations, nursing care procedures, and infection control procedures. Such review will be accomplished by the medical director, the director of nursing services and/or other personnel deemed appropriate by the medical director. Minutes of this review will be maintained and procedure manuals shall be annotated to reflect dated revisions.

(b) Director of Nursing Services. A registered professional nurse shall be responsible for proper performance of nursing services provided in the center.

(c) Qualification of Director of Nursing Services:

1. A graduate of a professional school of nursing

2. Currently licensed by the Alabama Board of Nursing

3. Have at least one year experience in surgical/ recovery nursing

4. Good mental and physical health

(d) Responsibilities of Director of Nursing Services.

1. Work within the framework of policies set forth by the facility

2. Develop nursing service policies and procedures

3. Develop a job description for each category of nursing service

4. Provide a thorough orientation for new nursing personnel including written verification of their competency

5. Provide supervision of nursing service personnel

6. Provide ongoing inservice education

7. Verification of license and physical examinations to ensure that they are current.

(e) Other required Nursing Service Personnel.

1. Operating Room

(i) Personnel in the operating room must include at least one (1) registered professional nurse to serve as the circulating nurse in each operating room. Additional personnel may include another RN, LPN or surgical technician to scrub.

2. Recovery Area(s)

(i) Personnel in each recovery area must include at least one (1) registered professional nurse or licensed practical nurse and supportive personnel as needed.

(ii) At least one registered professional nurse shall be on duty at all times while the center is in operation.

(f) Non-Nursing Service Personnel. Non-nursing service personnel, i.e., aides, housekeeping, office, etc., shall be assigned in sufficient numbers and with sufficient training to meet the needs of patients.

(g) CPR Trained Personnel. A person designated to perform cardiopulmonary resuscitation and at least one other person shall remain on the premises of the facility at all times during the work day or evening from the commencement of the first surgical procedure until all patients are discharged. Individuals designated to perform cardiopulmonary resuscitation shall be properly certified and shall attend a training course in cardiopulmonary resuscitation at least annually. Each facility shall maintain adequate staffing records to demonstrate that this requirement is met.

(4) Fire Evacuation Plan.

(a) Written Evacuation Plan. A written fire control and evacuation plan shall be maintained by each facility. In addition, necessary instructions and fire evacuation routes shall be posted in conspicuous places in the facility and shall be kept current.

(b) Fire Drills. Fire Drills shall be conducted at least quarterly and written observations of the effectiveness of these rehearsals shall be filed and kept for at least three (3) years.

(5) Communication Facilities.

(a) Call System. Arrangements shall be provided within the facility to summon additional personnel or help when or if needed in the event of emergency conditions. Requirements will depend on the size and physical configuration of the facility. In general, if all personnel (or occupants) are within hearing distance of any area of the facility, this would be deemed sufficient. Otherwise, there shall be a call system to all portions of the building normally occupied by persons in the facility.

(b) Telephones. There shall be an adequate number of telephones to summon help in case of fire or other emergency, and these shall be located so as to be quickly accessible from all parts of the building.

(6) Records and Reports.

(a) Medical Records to be Kept. An ambulatory surgical center shall keep adequate records including admission and discharge notes, histories, physical examinations, nurses notes, social service records, operative report, anesthesia record, informed consent, follow-up care, records of tests performed, and other records as indicated. The patients' records shall be current and kept in detail consistent with good medical and professional practice based on the service provided to each patient.

(b) Authentication of Records. All records shall be written, dated and signed in an indelible manner and made a part of the patient's permanent record.

(c) Filing of Records. All patient medical records shall be filed in a manner which will facilitate easy retrieval of any individual's record. If records are filed according to a number system, alphabetical cross-indexing shall be available.

(d) Storage of Records. Storage of records shall be in such a manner as to protect them from fire and water damage.

(e) Title to Records. Records of patients are the physical property of and kept in the facility and responsibility for control of them shall rest with the chief executive officer and governing authority.

(f) Records shall be Confidential. Records and information regarding patients shall be confidential. Access to these records shall be determined by the governing authority of the facility. Inspectors for licensure or other persons authorized by state or federal laws shall be permitted to review medical records as necessary for compliance.

(g) Preservation of Records. Medical records shall be preserved, either in the original or by microfilm for a period of not less than six years following the most recent discharge of the patient. In the case of a minor, records shall be kept for six years following the patient's obtaining legal age.

(h) Disposition of Records. When an ambulatory surgical center ceases to operate either voluntarily or by revocation of its license, the governing body (licensee) at or prior to such action shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted to the State Board of Health and shall contain provisions for the proper storage, safeguarding, and confidentiality transfer and/or disposal of patient medical records and x-ray files. Any ambulatory surgical center that fails to develop a plan for disposition of its records acceptable to the State Board of Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(i) Vital Statistics Report. A record shall be kept of all births, deaths, and stillbirths that occur within the center. By the fifth day of each month, the chief executive officer shall make a report of such births, deaths, and stillbirths for the preceding month on such form as the State Board of Health shall provide to the county health officer, or in counties without a county health officer, to the State Registrar. This report shall be in addition to the official birth, death, and stillbirth certificates. If there are no births, deaths, or stillbirths in any month, a report stating that fact shall be made to the county health officer.

(j) Personnel Records. The facility shall maintain a personnel record of each employee. As a minimum, the record shall include:

1. Application for employment that contains information regarding education, experience, and if applicable, registration and/or licensure information of the applicant, all physical examinations and evidence of continuing or inservice education.

(k) Operating Hours. The hours and days during which the center is open to the public and the hours for any intermittent specialty service centers not daily shall be conspicuously posted for public view and information.

(l) Health Examinations. As a minimum, each employee coming in contact with patients shall have a preemployment health examination by a physician. The examination is to be repeated annually and more frequently if indicated to ascertain freedom from communicable diseases. The extent of such examinations shall be determined by the medical director and documentation made in the employee's personnel folder. The examination shall include a chest x-ray or a tuberculin test.

(m) Operative Consent. Written informed consent for the performance of any surgical procedure must be obtained from the patient in every case. Consent by parent and/or guardian must be obtained if required by law.

(7) Patient Transfer and Transport.

(a) Transfer Agreement. Facility shall have a written agreement with one or more hospitals to ensure prompt referral and back-up services for patients requiring attention for an emergency or other condition necessitating hospitalization. Policies shall be developed relating to preoperative and postoperative transportation.

(b) 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 Alabama State Board of Health. 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, and upright position means no more than 20 degrees from vertical.

Author: Rick Harris
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420-5-2-.03 Patient Care.

(1) Admission and Examination Procedures.

(a) Admission. All persons admitted to the ambulatory surgical center shall be under the care of a medical staff member.

(b) History and Physical Examination. A complete medical history shall be obtained and recorded. A complete physical examination shall be made on all patients registered in the facility.

(c) Diagnostic and Treatment Services.

1. Ambulatory surgical centers operating a laboratory shall comply with Alabama Administrative Code, Chapter 420-5-8, Independent Clinical Laboratories. There shall be a physician's order for laboratory test(s) in the medical record and there shall be at least a copy of the report of results and date in the medical record that shall contain name and address of laboratory performing the test, and the initials of the individual performing the test. If the facility provides radiological services, it shall comply with Alabama Administrative Code, Chapter 420-5-7, Hospitals, rules governing the use of radiological equipment including required protection from radiation and calibration of all equipment used in this facility.

2. Laboratory work referred to outside sources shall be performed only by facilities which have been licensed by the State Committee of Public Health to perform such laboratory procedures. In the case of work sent to an out-of-state laboratory, said laboratory shall be licensed or possess a letter of exemption under the Clinical Laboratory Improvement Act (CLIA) for interstate licensure.

(2) Operative Procedures.

(a) Medical Services. Only physicians duly licensed in Alabama shall be permitted to perform physical examinations, order diagnostic work or medications, or perform surgery and medical procedures, except those procedures permitted by law to be undertaken by dentists or podiatrists. Only physicians, dentists, and podiatrists duly licensed in Alabama shall be permitted to perform such procedures. The governing authority or medical director shall delineate surgical privileges for each physician, dentist, and podiatrist performing surgery. It shall also establish written criteria setting forth the approved scope of treatment allowed in specific patient areas, including general and specific procedures that may not be performed by medical staff members.

(b) Permitted Procedures.

1. Facilities which comply with the requirements set forth in Subsection 3, below, may admit patients for the performance of surgical procedures for which the expected time for surgery and immediate recovery is less than 24 hours, and may retain patients with adverse conditions for a period of not more than 24 hours following admission. Facilities which elect not to comply with the requirements of Subsection 3 may admit patients for the performance of only those surgical procedures for which the expected time for surgery and recovery is not more than 12 hours and may retain patients with adverse conditions for a period of not more than 12 hours following admission. Judgments regarding the expected time for surgery and recovery shall be based upon reasonable medical opinion, taking into account both the ordinary and usual expectations associated with the procedure and the condition, circumstances, and prognosis of the individual patient.

2. Abortions shall not be performed in an ambulatory surgical center unless it is also licensed as an abortion or reproductive health center under Chapter 420-5-1, Abortion or Reproductive Health Centers, Alabama Administrative Code.

3. Facilities electing to be permitted to admit patients for periods in excess of 12 hours shall meet the requirements of Rule 420-5-2-.04(4)(e), and the following requirements, which are in addition to and not in lieu of requirements set forth elsewhere in these rules:

(i) Dietary Services.

(I) In the event that meals are prepared in the facility, the facility shall meet the requirements of Alabama Administrative Code, Chapter 420-5-7-.16, Hospitals, with the following exceptions:

420-5-7-.16(3)(a) - Number of Meals
420-5-7-.16(3)(b) - Timing of Meals
420-5-7-.16(5)(a) - Dining Room

In addition to meeting the requirements of 420-5-7-.16(l)(a) -- Direction and Supervision, the facility must provide a qualified food service manager and consultation by a licensed registered dietitian as required to meet the dietary needs of the patients.

(II) In the event that food is prepared outside the facility, such food preparation shall be performed only by facilities which meet the

requirements of Alabama Administrative Code, Chapter 420-3-14, Food Service Sanitation. In addition, the Ambulatory Surgical Center must provide a food preparation area with:

Double sink, if disposables are not utilized at all times

Microwave oven

Refrigerator

Handwashing sink counter space

Towel cabinet

Soap dispenser

Garbage cans with cover

Coffee maker

Storage area for silverware and cutlery, if disposables are not utilized at all times

(III) In all facilities, a floor pantry or diet kitchen readily available to the nursing unit shall be provided, and additional floor pantries or diet kitchens shall be part of each patient floor in all multistory facilities. The equipment provided shall be sufficient to furnish ice and between-meal nourishment to patients.

(ii) Radiological Services. The ambulatory surgical center shall maintain basic diagnostic radiologic services to fulfill the needs of its patients which shall meet the following standards:

(I) The radiologic services shall be free from radiation hazards for patients and personnel.

(II) Periodic inspection of equipment shall be undertaken, and hazards identified through such inspections or otherwise shall be promptly corrected.

(III) Radiation workers shall be checked periodically by the use of exposure meters or badge tests, to determine the amount of radiation to which they are routinely exposed.

(IV) A qualified radiologist, who may be full-time, part-time, or under consulting contract,

shall be employed to interpret those radiographic tests which, in the opinion of medical staff or the medical director require the special knowledge and skill of a radiologist.

(V) Only those personnel who are designated and certified as sufficiently qualified by the medical director, and who meet all requirements of state law, may operate radiographic equipment and administer radiographic procedures.

(VI) The radiologist or other medical practitioner who provides radiology services shall sign each report containing his/her interpretations.

(VII) The facility shall maintain each radiographic study and interpretation thereof for a period of not less than 5 years.

(iii) Laboratory Services. The ambulatory surgical center must have available at all times during which patients are admitted to the facility, clinical laboratory services appropriate to the needs of the patients as ordered by the attending physician or anesthesiologist.

(c) Anesthesia. General, regional, or local anesthesia shall be administered to patients only by one of the following:

1. An anesthesiologist.

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

3. A dentist or oral surgeon.

4. A podiatrist, but limited to administering local anesthetics to the foot or ankle.

5. A certified registered nurse anesthetist (CRNA) who is performing or assisting in any act involving the determination, preparation, administration, procedural ordering 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 or in coordination with a physician licensed to practice medicine, a podiatrist, or a dentist, who is immediately available.

6. An anesthesiologist assistant who is under the direction of an anesthesiologist who is immediately

available. Administration of general anesthesia or other treatments which would render a patient incapable of taking action for self-preservation in the event of an emergency is prohibited except when construction, storage, and equipment throughout the facility meet the standards of the National Fire Protection Association for Ambulatory Health Care Centers, LSC 101, 1985 edition. Flammable anesthetics are prohibited except when construction, storage, and equipment meet the standards of the National Fire Protection Association (NFPA) incorporated in Bulletin No. 56A "Standards for the Use of Inhalation Anesthetics."

(d) Examination of Tissue Removed. Examination of all tissue removed at the time of operation shall be performed by a pathologist certified or deemed Board eligible in anatomical pathology by the American Board of Pathology. A report of examination shall be placed in the patient's medical record. Tissue shall be disposed of in an appropriate manner following procedures set forth by the Alabama Department of Environmental Management.

(3) Postoperative Procedures.

(a) Postoperative Observation. Patients shall be observed in the facility for a reasonable period of time to ensure that no immediate postoperative complications are present. Individual patients must be discharged in an ambulatory condition without the need, in the opinion of the physician rendering treatment to the patient, for continuing observation or care by the ambulatory surgical facility. After discharge, patients shall not be provided additional observation or care by the facility in connection with the procedure performed during the admission. Provided, however, that patients may be readmitted to the facility for subsequent surgical procedures. In no event shall the total admission time exceed the periods set forth in Rule 420-5-2-.03(2)(b)(1), above. Patients requiring acute observation or care for longer periods shall be transferred to a hospital.

(b) Adverse Conditions. Patients in whom any adverse condition exists or in whom a complication is known or suspected to have occurred during or after the performance of the operative procedure shall remain in the facility or the back-up hospital until an uneventful recovery is assured as determined by the physician. However, patients requiring care for periods in excess of those set forth in Rule 420-5-2-.03(2)(b)1, above, shall be transferred to a hospital unless, because of the patient's medical condition, transportation to another facility would present a substantial danger to the patient's life or health. Any patient held in the facility as a result of such substantial danger shall remain under the care of a physician within the facility until the patient can be moved.

(c) Patient Instruction. Written instructions shall be issued to all patients upon discharge and shall include as a minimum the following:

1. Symptoms of complications to be looked for.

2. Activities to be avoided.

3. Specific telephone number of the operating physician or other knowledgeable professional staff member from the facility to be used by the patient should any complication occur or question arise.

4. The nearest hospital (and its location) to be used by the patient should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care at the hospital.

5. Date for follow-up or return visit after the performance of the operation as indicated by the condition of the patient.

6. Information on the availability of a near auxiliary health care (home health) service where indicated.

(4) Pharmaceutical Services.

(a) Administering Drugs and Medicines. Drugs and medicines shall not be administered to patients unless ordered by a physician duly licensed to prescribe drugs. Such orders shall be in writing and signed personally by the physician who prescribes the drug or medicine.

(b) Medicine Storage. Medicines and drugs maintained on the nursing unit for daily administration shall be properly stored and safeguarded in enclosures of sufficient size, and which are not accessible to unauthorized persons. Only authorized personnel shall have access to storage enclosures.

(c) Safety. Pharmacies and drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable federal laws.

(d) Narcotic Permit. Each center shall procure a controlled drug permit from DEA if a stock of controlled drugs is to be maintained. The permit shall be displayed in a prominent location.

(e) Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered.

(f) Medication Orders. All oral or telephone orders for medications shall be received by a registered nurse, a physician, or registered pharmacist and shall be reduced to writing on the physician's order record reflecting the prescribing physician and the name and title of the person who wrote the orders. Telephone or oral orders shall be signed by the prescribing physician within 48 hours. The use of standing orders will be according to written policy. Patients requiring medications outside of the facility shall be given a written prescription where medication can be obtained from a licensed pharmacy except in cases where the center has a licensed pharmacy as part of the center.

(g) Pharmacy. If the facility has a pharmacy, it shall be of sufficient size to permit orderly storage and accurate identification of all drugs and medicine, and avoid overcrowding of preparation and handling areas. The pharmacy shall comply with all state and federal regulations governing the operation of a pharmacy. The pharmacy shall be under the direction and supervision of a registered pharmacist. All compounding and dispensing of drugs shall be done by a registered pharmacist. In addition, the pharmacy shall also:

1. Be adequately lightened with artificial illumination.

2. Be provided with proper safeguards.

3. Be provided with a counter, sink and appropriate equipment.

4. Be provided with shelving.

5. Have a refrigerator.

6. Be provided with prescription files.

7. Be provided with books and equipment in accordance with requirements of the Alabama State Board of Pharmacy for compounding and dispensing of drugs.

(h) Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration.

(i) Emergency Kit or Emergency Drugs. Each center shall maintain, upon the advice and written approval of the facility's physician, an emergency kit of lifesaving medicines and equipment for the use of the physician in treating the emergency needs of patients. This kit shall be stored in such

a manner as to limit its access to authorized personnel but in such a manner as to allow quick retrieval.

(j) Drug Reference Sources. Each center shall maintain reference sources for identifying and describing drugs and medicines.

(5) Infection Control.

(a) Sterilization. Definitive written procedures governing sterilization techniques shall be developed. All equipment must be sterilized either by pressurized steam sterilization or gas sterilization. Procedures are to include:

1. Technique to be used for a particular instrument or group of instruments.

2. Length of time to accomplish sterilization.

3. A prohibition against reuse of one-time-use (disposable) items, unless the items have been reprocessed in accordance with federal law.

4. Temperature, time and pressure for steam sterilization.

5. Proper methods of preparation of items for sterilization (cleaning, wrapping, and dating).

6. Shelf storage time for sterile items.

7. Use of sterilizer indicators.

8. Methods of disposal of contaminated items such as needles, syringes, catheters, gloves, pathological waste, contaminated dressings, etc.

9. Use of routine (at least monthly) bacteriological sterilizer culture controls.

(b) Investigation of Infections. There shall be a committee established to investigate infections to determine, if possible, the origin of such infection. If the procedure was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence. In the event of sustained numbers of infections above average, the State Health Department shall be notified and operation of the facility discontinued until approval for continuation of operation is granted by the State Health Department.

(c) Infection Control Committee. An Infection Control Committee shall be composed of at least a physician and a registered nurse and other services as necessary.

(d) Reports of Infections. Reports of infections observed during the follow-up (or return) visit of the patient shall be made and kept as part of the administrative files. These reports shall be reviewed by the Infection Control Committee at least quarterly, but more often if necessary.

(e) Aseptic Techniques. Written effective procedures for aseptic techniques in the handling of patients are followed by all personnel. The procedures are reviewed at least annually for effectiveness and improvement.

(f) Linens. Linens used for draping must be sterilized. All reusable linens including those used as sterilizing wrappers are laundered before reuse. The facility has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

Author: Rick Harris
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420-5-2-.04 Physical Environment.

(1) Submission of Plans and Specifications.

(a) Scope. A facility constructed or renovated after the effective date of these rules shall be classified as Ambulatory Health Care Occupancy of the Life Safety Code, and Business Occupancy of the building code, and shall comply with the codes and standards adopted by the State Board of Health.

(b) New Construction, Additions, and Major Alterations. When construction is contemplated, for newbuildings, conversions, additions, or major alterations to existing buildings coming within the scope of these Rules, plans and specifications shall be submitted for review and approval to the Alabama Department of Public Health, in accordance with Alabama Administrative Code Rule 420-5-22, "Submission of Plans and Specifications for Health Care Facilities." Facilities shall comply with the requirements for Outpatient Surgical Facilities in the *Guidelines for Design and Construction of Hospitals and Health Care Facilities*, as adopted by the State Board of Health.

(c) Minor Alterations and Remodeling. Minor alterations and remodeling which do not affect the structural integrity of the building, which do not change functional operation, which do not affect fire safety, and which do not add beds or facilities over those for which the surgical center is licensed need not be submitted for approval.

(d) Inspections. The State Board of Health and its authorized representatives shall have access to the work for inspection wherever it is in preparation of progress.

(2) General.

(a) Location. The ambulatory surgical center shall be located in an attractive setting with sufficient parking space provided, with provisions for meeting the needs of the handicapped.

(b) Local Restrictions. The ambulatory surgical center shall comply with local zoning, building, and fire ordinances.

(c) Structural Soundness. The building shall be structurally sound, free from leaks and excessive moisture, in good repair, and painted at intervals to be reasonably attractive inside and out.

(d) Fire Extinguisher. An all-purpose fire extinguisher shall be provided at each exit and special hazard areas, and located so a person would not have to travel more than 75 feet to reach an extinguisher. Fire extinguisher shall be of a type approved by the local fire department or State Fire Marshal and shall be inspected at least annually. An attached tag shall bear the initials or name of the inspector and date inspected.

(e) Ventilation. The building shall be well ventilated at all times with a comfortable temperature maintained.

(f) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containerization, removal, or by a combination of these techniques. Infectious waste materials shall be rendered noninfectious on the premises by appropriate measures.

(g) Elevators. Multistory facilities shall be equipped with at least one automatic elevator of a size sufficient to carry a patient on a stretcher.

(h) Doors. Minimum width of doors to all rooms needing access for stretchers shall be 3 feet 8 inches wide and doors shall swing into rooms.

(i) Pest Control. The premises must be kept free from rodent and insect infestation.

(j) Corridors. Corridors shall comply with the following:

1. All rooms shall open onto corridor leading to exit.

2. Corridor used by patients shall be as a minimum 6 feet wide.

3. Service corridor may be as a minimum 4 feet wide.

(k) Occupancy. No part of an ambulatory surgical center may be rented, leased or used for any commercial purpose, or for any purpose not necessary or in conjunction with the operation of the center. Food and drink machines may be maintained or a diet kitchen provided.

(l) Lighting. All areas of the center shall have sufficient artificial lighting to prevent accidents and provide proper illumination for all services.

(m) Emergency Lighting. Emergency lighting systems shall be provided to adequately light corridors, operating rooms, exit signs, stairways, and lights on each exit sign on exterior at each exit in case of electrical power failure.

(n) Emergency Power. Emergency generator shall be provided to make equipment operable in case of power failure.

(o) Exits. Each floor of a center shall have two or more exitways remote from each other, leading directly to the outside or to a two hour fire resistive passage to the outside.

Exits shall be so located that the maximum distance from any point in a floor area, room or space to an exit doorway shall not exceed 100 feet except that when a sprinkler system is installed the distance of travel shall not exceed 150 feet.

(p) Exit Doors. Exit doors shall meet the following criteria:

1. Shall be no less than 44 inches wide.

2. Shall swing in the direction of exit and shall not obstruct the travel along any required fire exit.

(q) Exit Signs. Exits shall be equipped with approved illuminated signs bearing the word "Exit" in letters at least 4 1/2 inches high. Exit signs shall be placed in corridors and passageways to indicate the direction of exit.

(r) Interior Finish and Decorative Materials. All combustible decorative and acoustical material to include wallpaneling shall be as follows:

1. Materials on wall and ceiling in corridors and rooms occupied by four or more persons shall carry a flame spread rating of 25 or less and a smoke density rating of 450 or less in accordance with ASTM E-84.

2. Rooms occupied by less than four persons shall have a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASTM E-84.

(s) Floors. All floors in operating and recovery areas shall be smooth resilient tile and be free from cracks and finished so that they can be easily cleaned. All other floors shall be covered with hard tile, resilient tile or carpet or the equivalent. Carpeting is prohibited as floor covering in operating and recovery areas.

(t) Carpet. Carpet assemblies (carpet and/or carpet and pad) shall carry a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASTM E-84.

(u) Curtains. All draperies and cubicle curtains shall be rendered and maintained flame retardant.

(v) Handicap Facilities. The facility shall be accessible to the physically handicapped and shall comply with ANSI A117.1 "Making Buildings and Facilities Accessible and Usable by the physically Handicapped."

(3) Service Facilities. Facilities licensed prior to July 28, 2004, shall comply with the following.

(a) Admission Office. There shall be a room designated as the admission office where patients may discuss personal matters in private. The admission office may be combined with the business office and medical record room if privacy can be maintained when confidential matters are being discussed. This space shall be separated from the treatment area by walls and partitions.

(b) Waiting Room. A waiting room in the administrative section shall be provided with sufficient seating for the maximum number of persons that may be waiting at any time. Public toilets shall be available.

(c) Storage. A janitor's closet shall be provided in the administrative area and surgical suites.

4. Treatment Facilities. Facilities licensed prior to July 28, 2004, shall comply with the following:

(a) Examining Room. An examining room of sufficient size to have three feet of clearance at the end and sides of the examining table shall be provided. The examining room will contain a desk suitable for writing, a chair, a lavatory or sink for handwashing, instrument table and shelves or other equipment for storage of equipment as needed.

(b) Operating Room. Operating rooms shall be in accordance with current practices of NFPA 99, Health Care Facilities. Walls and ceilings shall have a smooth and washable surface. Size of room shall be as a minimum 12 feet by 12 feet.

(c) Scrub Area. Scrub-up space shall be provided convenient to the operating rooms. As a minimum, the following shall be provided:

1. Scrub sink with knee, elbow or foot controls

2. Soap dispenser

3. Single service towel dispenser

(d) Recovery Room. One or more recovery rooms containing beds for at least half the greatest number of procedures performed in any one day in any month shall be provided. Reclining type vinyl upholstered chairs or recovery stretcher may be substituted in lieu of beds. Other items for the patients' comfort may be provided in the room. Units for oxygen, resuscitation and suction shall be available in the recovery area.

(e) Post-Recovery Observation Rooms. Facilities electing to be permitted to admit patients for periods in excess of twelve hours shall meet the following requirements:

1. Observation rooms shall be so located as to minimize the entrance of odors, noise and other nuisances.

2. Observation rooms shall be directly accessible from the nursing/utility areas provided that accessibility from any public space other than the food service area will be acceptable. In no case shall a patient's room be used for access to another patient's room.

3. Patients' rooms shall contain a minimum of 120 square feet per bed for private room; 80 square feet per bed for rooms with two beds. No room shall house more than two patients. These dimensions shall not be construed as establishing a maximum.

4. There shall be sufficient space to permit nursing procedures and the placing of beds at least three (3)

feet apart and two (2) feet from the wall at the side of the bed.

5. Each bed in semiprivate rooms must have ceiling suspended curtains which extend around the bed to provide total visual privacy, in combination with adjacent walls and curtains.

6. Accommodations for each patient shall include:

(i) A separate bed of proper size and height for the convenience of the resident.

(ii) A clean, comfortable mattress.

(iii) Bedding appropriate to the weather and climate.

(iv) Functional furniture appropriate to the patient's needs, and individual closet space in the room with clothes racks and shelves accessible to the resident or to a significant other.

7. Each post-recovery observation room shall be equipped with or located near a toilet. Safety hand grips shall be provided at each toilet, and meet ANSI guideline requirements for grab bars.

8. The nurses' station must be equipped to receive patient calls through a communication system from both observation rooms and the toilet.

9. Provision must be made for storage of sufficient clean linens to accommodate all observation beds.

(f) Clean Workroom. A clean workroom shall be provided sufficient in size to process and store clean and sterile supply materials and equipment and must contain a work counter and sink.

(g) Sterilization. An autoclave must be provided, adequate in size to sterilize the equipment in use.

(h) Soiled Workroom. The soiled workroom shall contain a clinical sink or equivalent flushing rim fixture, handwashing sink, work counter, waste receptacle, and linen receptacle.

(i) Toilets. At least one toilet and lavatory with a soap dispenser and disposable towel dispenser shall be provided for each recovery room. Toilet facilities shall be provided at no less than one toilet facility per ten recovery beds.

(j) Locker Room. Provide nurses and doctors locker/change rooms. The locker rooms shall contain lockers, water closet, lavatory and change area.

(k) Refrigeration. A refrigerator shall be provided with provisions for safeguarding drugs. The refrigerator shall maintain drugs at a temperature of 42 degrees F. + 6 degrees F. A separate refrigerator shall be provided for snacks, juices, etc., which may be required by patients.

(l) Outpatient Surgery Change Area. A separate area shall be provided where outpatients can change from street clothing into hospital gowns and be prepared for surgery. This shall include holding room(s), lockers, toilets separated as to sex, and clothing change or gown area(s).

(m) Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area which contains a counter and a sink. Where possible this area shall be located in such a manner to prevent contamination of medicines being prepared for administration.

(5) Housekeeping Services.

(a) Personnel. Sufficient personnel are employed to maintain the facility clean and orderly. Primary patient care personnel shall not perform routine decontamination and housekeeping duties during periods in which they are caring for patients.

(b) Techniques. Written procedures outlining techniques to be followed in routine housekeeping and decontamination are developed and followed. Procedure rooms must be cleaned using appropriate disinfectants to assure asepsis between each procedure as approved by the Infection Control Committee.

(6) Soiled Linen/Trash Collection Rooms. Rooms used for the collection or storage of soiled linen or trash, constructed after July 28, 2004, shall have a one hour wall with at least a 45 minute self closing door enclosing the room, separating the room from the rest of the family.

Author: Victor Hunt
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