

APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 420
Department or Agency: Alabama State Board of Health Alabama Department of Public Health Division of Licensure and Certification
Rule No.: 420-5-2-.03
Rule Title: Patient Care
Intended Action: Amend

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved? No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facets of the rule-making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer

Sancha Howard
Sancha Howard

Date

Thursday, September 19, 2024

REC'D & FILED
SEP 19, 2024
LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LICENSURE AND CERTIFICATION

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NO. & TITLE: 420-5-2-.03 Patient Care

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

This amendment will allow for the Department to address administration of anesthesia under the direct supervision of a licensed physician or in coordination with an available licensed physician.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

A public hearing will be held on October 24, 2024, at 10:30 a.m. at the RSA Tower, Suite 982, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Monday, November 4, 2024

CONTACT PERSON AT AGENCY:

Jacqueline D. Milledge
Bureau of Health Provider
Standards
Department of Public Health
P.O. Box 303017
Montgomery, Alabama 36130-3017
Telephone Number: (334) 206-5259

Sancha Howard

Sancha Howard

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

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 Board of 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~~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 ~~twenty-four hours, and may retain patients with adverse conditions for a period of not more than twenty-four hours following admission.~~ Facilities which elect not to comply with the requirements of subsection 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 ~~twelve hours and may retain patients with adverse conditions for a period of not more than twelve~~ 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(1)(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~~Double sink, if disposables are not utilized at all times—~~microwave~~

Microwave oven

~~refrigerator~~Refrigerator

~~handwashing~~Handwashing sink counter space

~~towel~~Towel cabinet

~~soap~~Soap dispenser

~~garbage~~Garbage cans with cover

~~coffee~~Coffee maker

~~storage~~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 ~~five~~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 a Certified Registered Nurse Anesthetist, by an Anesthesiologist Assistant licensed by the Alabama Board of Medical Examiners, or by a qualified physician. The anesthesia must be administered ~~only~~ under the direct supervision of a licensed physician or in coordination with a licensed physician 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~~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

Statutory Authority: Code of Ala. 1975, §§22-2-2(6), et seq.;
22-21-28, et seq.

History: Filed September 1, 1982. **Amended:** Filed February 20, 1991. **Amended:** Filed August 22, 2005; effective September 26, 2005. **Amended:** Filed October 20, 2005; effective November 24, 2005. **Amended:** Published ; effective .