**ALABAMA STATE COMMITTEE OF PUBLIC HEALTH**
**ALABAMA DEPARTMENT OF PUBLIC HEALTH**
**BUREAU OF ENVIRONMENTAL AND HEALTH SERVICE STANDARDS**
**DIVISION OF LICENSURE AND CERTIFICATION**
**ADMINISTRATIVE CODE**

# CHAPTER 420-5-5
# END STAGE RENAL DISEASE TREATMENT AND TRANSPLANT CENTERS

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## 420-5-5-.01 General.

(1) Legal Authority.

(a) Adoption of Rules. Under and by virtue of authority vested in it by the Legislature of Alabama, Code of Ala. 1975, Sections 22-21-20, et seq., the State Board of Health does hereby adopt and promulgate the following Rules governing the operation of End Stage Renal Disease Treatment and Transplant Centers in the State of Alabama.

(b) End Stage Renal Disease Treatment and Transplant Centers. For the purpose of these Rules "End Stage Renal Disease Treatment and Transplant Centers" shall include facilities that are intended to treat persons suffering permanent and irreversible kidney failure, who require dialysis on a regular maintenance basis, or who may be of suitable candidates for kidney transplantation. The facilities that are classified under these Rules as "End Stage Renal Disease Treatment and Transplant Centers" are further defined in these Rules as Renal Dialysis Centers, Renal Dialysis Facilities and Renal Transplantation Centers.

(2) Definition (A list of selected terms often used in connection with these Rules):

(a) "AAC Rule" means *Alabama Administrative Code* Rule.

(b) "Anticoagulant" means a medication or medical technique to prevent or slow down coagulation and clotting.

(c) "Anticoagulation" means the process of inhibiting the blood clotting mechanism by the administration of certain drugs.

(d) "Artificial Kidney" means apparatus which removes metabolic wastes or other poisons from the body when the natural kidneys are not functioning properly. This apparatus may be referred to as a kidney dialysis unit.

(e) "Chief Executive Officer" means a person who is delegated the responsibility for the interpretation, implementation and proper application of policies and programs established by the governing authority. The CEO must meet one of the following requirements to be qualified:

1. Holds at least a Baccalaureate Degree and has at least 1 year of experience in a dialysis unit.

2. Is a qualified registered nurse or qualified physician director.

(f) "Chronic Hemodialysis" means Hemodialysis over a long period of time, usually to the extent of the patient's life or organ transplant.

(g) "Dialysis" means the diffusion of dissolved material through a semipermeable membrane; as used in these Rules a cleansing process using dialyzing equipment (artificial kidney) and appropriately recognized procedures.

(h) "Dietitian (Qualified)" means a person who (a) is eligible for registration by the American Dietetic Association or (b) has a baccalaureate degree with major studies in food and nutrition, dietetics or food service management and has 1 year of supervisory experience in the dietetic service of a health care institution and participates annually in continuing dietetic education.

(i) "Governing Authority" means owner(s), Hospital Association, County Hospital Board, 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/or maintaining an End Stage Renal Treatment and/or Transplant Center, either hospital or non-hospital based.

(j) "Hepatitis" means inflammation of the liver, usually due to a viral infection, but can result from toxic agents or medications.

(k) "Medical Staff" means physicians, certified registered nurse practitioners, and physician assistants who are

privileged by agreement with the Renal Dialysis Center or facility to attend patients within the institution.

(l) "Physician-Director (Qualified)" means the physician responsible for planning, organizing, conducting and directing the Renal Dialysis Services. The Physician-Director must meet one of the following requirements to be considered qualified:

1. Is Board eligible or Board certified in nephrology medicine by a professional Board and has had at least 12 months of experience or training in the care of patients at Renal Dialysis Facilities.

2. During the 5 year period prior to the effective date of these Rules, served for at least 12 months as Director of a Dialysis Program.

(m) "Peritoneal Dialysis" means dialysis using the peritoneum as a dialysis membrane.

(n) "Recipient Registry" means registry maintained for dialysis patients who are awaiting donor transplantation.

(o) "Registered Professional Nurse - (Qualified)" means that person responsible for the nursing services in the Renal Dialysis Center or Facility. The registered nurse must meet one of the following requirements to be recognized as qualified:

1. A person who holds current licensure and registration as a registered nurse by the State of Alabama Board of Nursing and;

(i) Has at least 12 months experience in clinical nursing and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process, or;

(ii) Has 18 months of experience in nursing care of the patient or maintenance dialysis or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process.

2. If the qualified registered nurse responsible for the nursing service is in charge of self-care dialysis training, this person must have at least 3 months of the total required renal dialysis experience in training patients in self-care.

(p) "Renal Dialysis Center" means a hospital unit that does not perform renal transplant, but is approved to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement), and rehabilitative services for the care of renal dialysis patients.

(q) "Renal Dialysis Facility" means:

1. A hospital based facility which furnishes end stage renal dialysis treatment on inpatients or outpatients but do not provide a full spectrum of diagnostic, therapeutic and rehabilitative services.

2. A non-hospital based facility which furnishes end stage renal dialysis treatment to non-hospitalized patients but does not provide a full spectrum of diagnostic, therapeutic and rehabilitative services.

(r) "Renal Transplantation Center" means a hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the End Stage Renal Disease transplant patients including dialysis furnished directly or under arrangements. A Renal Transplantation Center may also be a Renal Dialysis Center.

(s) "Self-Care Dialysis Training" means a program which trains renal disease patients or their helpers, or both, to perform self-care dialysis either in the center/facility or at home.

(t) "Social Worker - (Qualified)" means that person who is responsible for providing social services to renal disease patients on maintenance dialysis or self-care training in the center/facility. The person to be considered qualified must meet one of the following requirements:

1. Completion of a course of study with specialization in clinical practice, and hold a masters degree from a graduate school of social work accredited by the council on social work education and meet the requirements of "the Alabama Social Work Board of Examiners."

2. Has a Bachelor's Degree and meets the requirements of "the Alabama Social Work Board of Examiners" and has served for at least two years as a social worker, one year of which was in a dialysis unit or transplantation program prior to the effective date of these Rules.

(u) "These Rules" means Rules 420-5-5-.01 through 420-5-5-.04, Chapter 420-5-5, End Stage Renal Disease Treatment and Transplant Centers, Alabama Administrative Code.

(v) "Water Treatment" means the process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets ASAIO-AAMI (American Society of Artificial External Organs-Association for the Advancement of Medical Instrumentation) 1977 Standards for water for Hemodialysis.

(3) Types of License.

(a) Regular License. A regular license may be granted by the State Board of Health after the Board has determined that the End Stage Renal Disease Center is in substantial compliance with the Rules herein adopted.

(b) Temporary License.

1. At its discretion, the State Board of Health may grant a license which indicates a temporary condition of non-compliance with these Rules. A temporary license may be granted when the Board 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 successive one year terms.

2. An End Stage Renal Disease and Treatment Center may be granted a temporary license prior to opening if in compliance with the provision of these Rules relative to the physical plant and staffing. The license granted under Alabama Administrative Code Rule 420-5-5-.01(3)(b) shall be valid until a regular license is granted or December 31 of the year in which the license was issued. A temporary license may be re-granted under *Alabama Administrative Code* Rule 420-5-5-.01(3)(b) when it has been demonstrated to the Board that specific efforts are being made to comply with these Rules.

3. End Stage Renal Disease and Transplant Centers which are in existence on the effective date of these Rules may be granted a temporary license under one or more of the following conditions:

(i) Where failure to qualify for a regular license is due to higher requirements of these Rules.

(ii) Where the governing authority is making specific plans to construct a new facility to establish an End Stage Renal Disease and/or Transplant 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 Board of Health.

4. End Stage Renal Disease and Transplant Centers which have been granted a temporary license in lieu thereof when an official inspection shows that the maintenance and operation of the center does not substantially meet the requirements for a regular license.

(c) Probational License. At its discretion, the State Board of Health may grant a probational license under one or more of the following conditions, and then only when the Board is satisfied notwithstanding the deficiency, 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 year not to exceed two successive one year terms.

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

2. When the Board has reason to believe the facility is not making specific plans to comply with these Rules or the End Stage Renal Disease Center's ability is questionable.

3. Conduct or practices not deemed by the Board to be in the patient's best interest for example; unethical, fraud or abuse, aiding or abetting the commission of an illegal act.

(4) Licensing.

(a) Application for License. All facilities except those that are in and under the direct control of a license hospital shall apply for licensure on a form designated by the State Board of Health. The application will reflect all data required by the Code of Ala. 1975, Section 22-21-20 et seq. and shall be submitted with either a Certificate of Need (CON) or letter of non-reviewability obtained from the State Health Planning Agency.

(b) Fee. See Code of Ala. 1975, Section 22-21-20 et seq.

(c) Name of Facility. Every End Stage Renal Disease Treatment and Transplant 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 Licenses. 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 grounds used by the same facility.

(e) Re-issuance of License Certificate. A new license may be issued under certain circumstances:

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

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

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

(iii) Physical Relocation.

(iv) Station Increase (fee required).

2. The governing authority shall file with the State Board of Health an application for license 30 days before any proposed change requiring a new license certificate in order to permit processing of the application and issuance of the license certificate prior to the desired effective date of the change.

(f) Hospital Owned and Controlled Facilities.

1. An End Stage Renal Disease Treatment and/or Transplant Center located within a licensed hospital and is controlled and organized as a department of the hospital will not be licensed as a separate entity of the hospital.

2. A hospital owned and controlled End Stage Renal Disease Treatment and/or Transplant Center located within the hospital will be subjected to these Rules and will be applied as part of the Hospital Licensure Program.

(5) **Right of Appeal.** Any licensee dissatisfied with administrative decisions made in the application of these rules. may appeal under the Alabama Administrative Procedures Act, Code of Ala. 1975, Sections 41-22-1 et.seq., and the State Board of Health Rules for the Hearing of Contested Cases, Alabama Administrative Code Chapter 420-1-3.

(6) **Waivers.** Waivers from these rules may be requested in accordance with the provisions of the Alabama Administrative Procedures Act, Code of Ala. 1975, Sections 41-22-1 et.seq., and

the State Board of Health Rules for the Hearing of Contested Cases Alabama Administrative Code Chapter 420-1-3-.09.

(7) Unusual Occurrences. Unusual occurrences which threaten the welfare, safety and health of patients, personnel or visitors shall be reported by the ESRD facility within 24 hours, either by telephone (and confirmed in writing), or by facsimile to the Alabama Department of Public Health, Division of Health Care Facilities, and other agencies/authorities as required. Examples of unusual occurrences that must be reported include: include: misuse of medical devices or medications, defective devices, suspected cases of patient abuse or neglect, life threatening burns, fires or other catastrophic occurrences, medical conditions or deaths that occur as the result of unusual circumstances. Any acute event that results in a patient receiving emergency treatment must be reported. Emergency treatment includes unscheduled transportation to a hospital or receipt of cardiac life support from a hospital, ambulance service or rescue squad, or staff member. Also to be reported are outbreaks of infectious diseases or any condition in the facility, including the water treatment system, which would necessitate the temporary or long term closure of the dialysis facility (excluding inclement weather).

(8) **Disclosure of Information.** Official reports, such as Statements of Deficiencies generated by the State Board of Health as a result of on-site inspections, and plans of corrections submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the license of this facility or another facility operated by the same governing authority. Inspection reports will never contain the name or other identification of any patient or client in the inspected facility.
**Author:** Rick Harris
**Statutory Authority:** Code of Ala. 1975, §§22-21-20, et seq.
**History:** Filed September 1, 1982. **Amended:** Filed May 22, 1990.
**Amended:** Filed September 20, 2001; effective October 25, 2001.
**Amended:** Filed November 13, 2007; effective December 18, 2007.

**420-5-5-.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

staff (or in the absence of an organized medical staff) a 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. Appointments and duties of the chief executive officer.

5. Requirement that the medical staff (if such exists) be organized in accordance with bylaws approved by the governing authority.

6. Mechanism for appointment of medical staff members and a medical director.

7. Mechanism for approval of medical staff bylaws and policies governing activities of the medical director if an organized medical staff does not exist.

(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 have executive authority and be responsible 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.

(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. Policies and procedures shall be developed to include the following areas:

1. Patient admission and discharge. These shall be for both in-facility care and self-care or home care.

2. Requirement for a complete history and physical examination on admission and at least annually.

3. Required diagnostic procedures.

4. Patients waiting for renal transplant must be typed initially for Human Leukocytes Antigens (HLA) and screened for antibodies to HLA. The facility must complete an Agreement or Arrangement with a State licensed and/or CLIA licensed Histocompatibility Laboratory which contains the provision for HLA typing and antibody screening, including the frequency of antibody screening.

(3) Self-Care Dialysis. Self-Care Dialysis Training Program. If the facility offers self-care dialysis training, a qualified registered nurse is in charge of the training. Appropriate records of this training shall be maintained in the patient's record.

(4) Use of Outside Resources. Contractual Service Agreements. There are written contractual agreements and arrangements for services which the facility or its employees do not provide directly. The agreement or arrangement delineates the responsibilities, functions, objectives, and services provided by the outside resource and is signed and dated by an authorized representative of the facility and the person or agency providing the service.

(5) Fire Evacuation Plan.

(a) Written Evacuation Plan. A written fire control and evacuation plan shall be maintained by each facility. In addition, necessary instruction 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 years.

(6) Communication Facilities.

(a) Personnel Paging Systems. Arrangements shall be provided within the facility to summon additional personnel or help when, or if needed, in the event of emergency conditions. 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 personnel of 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.

(7) Records.

(a) Responsibility for Medical Records. There is a qualified member of the facility's staff designated to serve as supervisor of medical records.

(b) Maintenance and Content of Medical Records.

1. The facility maintains complete medical records on all patients, including those receiving care within the facility and those self-care or home dialysis patients for whom the facility has assumed responsibility. These medical records shall be maintained in accordance with acceptable professional standards and practices.

2. Each patient's record shall contain sufficient information to identify the patient clearly, to justify the diagnosis and treatment and to accurately document the rendition and results of treatment.

3. The medical record shall contain physicians' orders for all medications to be administered, treatments to be given and services to be rendered.

4. Nurses' notes records shall be maintained for each patient in the facility. In addition to regular entries concerning special diets and medications administered, personal services rendered and observations made, other notes, which may be of importance to the attending physician or other nursing personnel shall be annotated.

5. Nurses' notes and physician orders shall be kept at the nurses' station while current and shall be placed in the patient's file folder when completed.

6. All entries on all records and reports shall be legibly written in ink or typewritten.

7. A physician may use a rubber stamp signature to sign records and reports, if that physician has submitted a letter, kept on file in the facility, indicating that the rubber stamp is for his own use and will not be used by any other personnel within the facility.

(c) Completion and Organization of the Record.

1. Current medical records and those of discharged patients are completed promptly (not to exceed 15 days after discharge or death) and all clinical information pertaining to a patient is centralized in the patient's medical record.

2. The medical record shall be organized in such a manner as to retrieve information readily. If numerical indexing is used, an alphabetical cross-reference is utilized to facilitate retrieval.

(d) Confidentiality of Medical Records. When an individual enters an End Stage Renal Disease Treatment or Transplant Center, records and information regarding him are confidential. Information shall not be shared with visitors, other patients, or anyone not having responsibility for his care. Access to these records shall be limited to designated staff members, physicians and others having professional responsibility, and to representatives of the State Board of Health.

(e) Storage and Protection of Medical Records.

1. The facility maintains adequate facilities, equipment, and space conveniently located to provide efficient processing of medical records and other medical information.

2. The medical record shall be protected against loss, destruction (from water and fire damage) or unauthorized use. The facility has written policies and procedures which govern the use and release of information contained in the medical record. A medical record shall be maintained for six years after discharge of patient, or six years after patient reaches majority under State law, whichever is longer.

(f) Transfer of Medical Information. The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities.

(g) Personnel Records. A personnel record shall be maintained for each employee. The personnel record shall include application for employment, which contains information

regarding education, training, experience, and if applicable, registration and/or licensure information of the applicant, and record of physical examinations. The names and qualification of all professional employees shall be kept on file for inspection by the State Board of Health.

(h) Disposition of Medical Records. When an End Stage Renal Disease Treatment or Transplant 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 plans shall be submitted to the Alabama Department of Public Health for approval and shall contain provisions for the proper storage safeguarding and confidentiality, transfer and/or disposal of patient's medical records and x-ray files. Any center that fails to develop such plans of disposition of its records acceptable to the Alabama Department of Public Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(8) Housekeeping Services.

(a) Personnel. Sufficient personnel are employed to maintain the facility clean and orderly. Personnel utilized in nursing and other activities may be utilized to perform routine housekeeping chores, however, specific written instructions to eliminate possible sources of cross-contamination must be developed. Primary patient care personnel shall not perform general decontamination and housekeeping chores 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 maintained. Procedure rooms and areas must be cleaned, using appropriate disinfectants, between each procedure.

(c) Premises. The premises shall be kept neat and clean, and free of accumulation of rubbish, weeds, ponded water, or other conditions of similar nature which would have a tendency to create a health hazard.

(d) Control of Insects, Rodents, etc. The facility shall be kept free of ants, flies, roaches, rodents and other vermin. Proper methods of their eradication or control shall be utilized.

(e) Toilet Room Cleanliness. Floors, walls, ceilings, and fixtures of all toilet rooms shall be kept clean and free of objectionable odors. These rooms shall be kept free from an accumulation of rubbish, cleaning supplies, toilet articles, etc.

(f) Housekeeping Facilities and Services. Housekeeping facilities and services are required to be such that comfortable and sanitary conditions for patients and employees are constantly maintained.

(g) Equipment and Supplies. The facility shall maintain an adequate quantity of housekeeping and maintenance equipment and supplies.

(9) Infection Control.

(a) Policies and Procedures. There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. The policies and procedures support sound patient care and promote good personal practices and include appropriate aseptic and isolation techniques to be used.

(b) Sterilization. Definitive written procedures governing sterilization techniques shall be developed. Pressurized steam sterilization is the preferred method; however, gas sterilization and soaking of some types of equipment or instruments in a bacteriocidal solution of approved efficacy may be permitted. 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. Prohibition against reuse of one-time use (disposable) items with the exception of renal dialyzers and dialyzer lines provided a written processing protocol for reuse is submitted to the Alabama Department of Public Health.

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, etc.

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

(c) Investigation of Infections. Reports of infections such as abscesses, septicemia, hepatitis, or other communicable

diseases observed during admission or follow-up (or return) visit of the patient shall be made and kept as a part of the administrative files. Efforts shall be made to determine the origin of any such infection and if the procedure was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

(d) Hepatitis Surveillance.

1. Routine surveillance of patients and staff for HBV infection is essential to determine if transmission is occurring in the unit. The HBsAg (anti-HBs) status of all patients and staff shall be known to identify those individuals who are;

(1) HBsAg-positive and therefore potential sources of infection to others;

(2) anti-HBs-positive and therefore, immune; and

(3) HBV-seronegative and therefore susceptible to HBV.

2. Patients for dialysis and new employees must be screened for HBsAg and anti-HBs before or at the time they enter the unit in order to determine their serologic status for surveillance purposes. HBsAg positivity in staff does not necessarily preclude employment in the dialysis center; these persons may be managed in the same manner as employees who seroconvert to HBsAg-positive status while working in the unit.

3. The HBsAg status of visiting and home patients must be known, if possible, at the time of admission to determine if they are potential sources of infection.

4. The most sensitive test methods available for HBsAg and anti-HBs detection must be employed.

5. Patients who are seronegative (HBsAg- and anti-HBs-negative) must be tested once a month for HBsAg, serum glutamic oxalacetic transaminase (SGOT), and/or serum glutamic pyruvic transaminase (SGPT) and at least once every three months for anti-HBs. Seronegative staff members must be tested at least once every six months for HBsAg and anti-HBs.

6. Patients and staff who have had hepatitis B as demonstrated by:

(1) a documented history of hepatitis B;

(2) HBsAg-positivity demonstrated on two occasions; or

(3) a positive HBsAb test in the absence of an injection of hepatitis B immune globin, need have only further HBsAb determinations on an annual basis for hepatitis surveillance purposes.

7. Patients and staff who have received a full course (3 injections over a six-month period) of Heptavax vaccine and have a positive HBsAb test need only further HBsAb determinations on an annual basis for hepatitis surveillance purposes.

(e) Cross-Contamination Prevention.

1. The facility must employ appropriate techniques to prevent cross-contamination between the dialysis unit and adjacent hospital or public areas.

2. There must be some type of protective covering, either plastic, disposable, or launderable, during the time when blood lines are opened or needles inserted or withdrawn in order to prevent the patient's street clothing from becoming contaminated.

3. All equipment utilized in dialysis must be changed or cleaned after each use.

4. Appropriate precautionary measures must be implemented to prevent facility personnel from contaminating shoes and clothing that will be worn outside the dialysis unit.

(f) Disposal of Infectious Material and Waste. Policies and procedures must be developed for the proper handling, cleaning and disposal of all infectious material and waste products. All dialysis waste must be contained in a closed sewage drain system.

(g) Isolation Facilities.

1. An isolation dialysis room must be provided for all Hepatitis B Antigen Positive Dialysis Patients; the room must be partitioned from treatment areas for Hepatitis B Antigen Negative Patients and provide separate facilities from toilet, handwashing, janitorial, drug storage, blood (Hematocrit and clotting time) handling and waste storage and disposal.

2. Facilities not equipped with a Hepatitis B Isolation Section as defined above may not accept for treatment any Hepatitis B Antigen Positive Patients but must complete

an Agreement to transfer any Positive Patients to a facility so equipped.

(h) Infection Control Committee. A committee must be established and made up of at least a physician and the Director of Nurses to evaluate or monitor staff performance, review all policies and procedures at least annually, and review infectious cases. This committee shall meet at least monthly.

(i) Linens.

1. All reusable linens, including those used as sterilizing wrappers, must be laundered before reuse.

2. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

3. The facility has available at all times a quantity of linen essential for proper care and comfort of patients.

(j) Water Treatment. Water used for dialysis purposes must be analyzed at least monthly for bacteria and at least six months for chemicals. The water must be treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Records of test results and equipment maintenance are maintained at the facility.

**Author:** Tigner Zorn, Carol Nason, Jim Prince, Rick Harris
**Statutory Authority:** Code of Ala. 1975, §§22-21-20, et seq.
**History:** Filed September 1, 1982. **Amended:** Filed November 19, 1987. **Amended:** Filed October 18, 1996; effective November 22, 1996. **Amended:** Filed September 20, 2001; effective October 25, 2001.

**420-5-5-.03 Patient Care.**

(1) General.

(a) Medical Supervision and Emergency Coverage. The facility ensures that the health care of each patient is under the continuing supervision of a physician and that a physician is available 24 hours a day, seven days a week for emergency situations. A roster of physicians providing emergency services is posted at the nurses' station.

(b) Patient Care Policies. The facility shall have written patient care policies relating to all areas of care, and are developed by the physician director or medical staff and approved by the governing body. The patient care policies are

reviewed periodically to determine effectiveness, but at least annually.

(c) Patient Long-Term Program and Patient Care Plan.

1. The facility maintains for each patient a written long-term program and patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality.

2. The long-term program states that most suitable treatment modality (dialysis or transplantation) and the most suitable dialysis setting (facility or home). The program is developed by a professional team and the patient, is formally reviewed and revised as necessary, and accompanies the patient on inter-facility transfer.

3. The patient care plan is developed by a professional team and the patient, and is based on the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs. The patient care plan is personalized for the individual, reflects the ongoing psychological, social and functional needs of the patient. It is reviewed at least semi-annually.

4. The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and prescribes, with input from other professional personnel involved in the care of the patient, a planned regimen of care.

(d) Admission and Discharge Policies and Procedures. Policies and procedures must be developed for admission and discharge of in-facility care, self-care and home-care patients.

(e) Medical History and Physical Examination. A complete patient medical history and physical examination must be obtained and recorded. The physical examination and history must be made prior to or on the date of admission and the patient must be re-examined on an annual basis.

(f) Patient Rights. Policies regarding the rights and responsibilities of patients shall be established. These policies must be made available to patients, any guardians, next-of-kin and sponsoring agencies. The staff of the facility must be trained and involved in the implementation of these policies and procedures. Patients must be fully informed by a physician of their medical condition, unless medically contraindicated (as documented in their medical records).

(g) Patient Transport. 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.

(2) **Emergency Services**

(a) Emergency Supplies and Equipment. Each End Stage Renal Disease Treatment and Transplant Center must, with the advice of the facility's Medical Director, develop policies and procedures relating to the care and treatment of patients experiencing an emergent situation.

(b) Basic Life Support. Each End Stage Renal Disease Treatment and Transplant Center shall be equipped with an Automated External Defibrillator ("AED"). The AED must be maintained and charged at all times according to manufacturer's instructions. A person designated to perform cardio-pulmonary resuscitation ("CPR") and operate the AED and at least one other staff member must be present whenever any patient is in the facility. Individuals designated to perform CPR and operate the AED must be properly certified and attend a training class on CPR and the operation of an AED at least annually.

(c) Advanced Life Support. Each End Stage Renal Disease Treatment and Transplant Center is responsible for ensuring that patients have timely access to Advanced Cardiac Life Support ("ACLS"). A facility ensures timely access to ACLS if:

1. The facility is located within ten miles of a hospital;

2. The facility is located within ten miles of a rescue squad or ambulance service with ACLS capabilities; or,

3. The facility designates a staff member to perform ACLS. Individuals designated to perform ACLS must be properly certified and trained, and must be present whenever any patient is in the facility. The facility must be equipped with a crash cart that includes all appropriate unexpired ACLS drugs and airway management devices in sizes and quantities appropriate for their patients; and monitor(s); and a manual defibrillator.

(3) Nursing Services.

(a) Director of Nurses. A qualified registered professional nurse must be in charge of nursing services of the facility.

(b) Required Qualified Registered Professional Nurses. At least one qualified registered professional nurse must be on duty at all times while dialysis is in progress to oversee patient care.

(c) Required Supportive Personnel. Supportive personnel (RNs, LPNs, dialysis technicians) shall be assigned to ensure that the needs of the patients are met.

(d) Job Descriptions. The authority, responsibilities, and functions of each category of nursing personnel shall be clearly defined in writing.

(e) Physical Examinations.

1. A pre-employment physical examination and a test for hepatitis, as indicated under Alabama Administrative Code Rule 420-5-5-.02(9)(d) shall be required of all new employees. Provisions shall be made for re-examination at intervals not to exceed twelve months. A re-examination for hepatitis must be in accordance with Alabama Administrative Code Rule 420-5-5-.02(9)(d).

2. The pre-employment physical examination shall include a skin test for tuberculosis. If the skin test is negative, no further skin testing or examinations are required. If the skin test is positive, a chest x-ray shall be made. If the chest x-ray is essentially negative, INH preventive therapy is highly recommended unless there are contraindications.

(f) Personnel Policies and Procedures. The facility maintains and implements written personnel policies and procedures that support sound patient care and promote good nursing practice.

(g) Training of Personnel. There shall be an effective program of training established for all personnel. A record of this training shall be developed to indicate training given, performance of the individual and acceptable completion of the program. The record shall be maintained in the individual's personnel folder. All trainees shall be under the direct supervision of qualified professional personnel.

(h) Availability of Materials. Personnel manuals, minutes of staff development programs and other pertinent materials shall be updated periodically and made available to all personnel involved in patient care.

(i) Staff Development. An ongoing educational program is planned and conducted at least monthly for the development and

improvement of skills of all the facility's clinical personnel, including training related to problems and needs of the renal dialysis patient. Records shall be maintained of programs presented and personnel attending. Each employee receives appropriate and thorough orientation to the facility and its policies and to the employee's position and duties.

(4) Storage, Preparation and Handling of Drugs and Medicines.

(a) Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients nor to anyone within or outside the facility unless ordered by a physician, certified registered nurse practitioner or physician assistant duly licensed to prescribe drugs. Such orders shall be in writing and signed by the individual with privileges in the facility, 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. Narcotics and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable State and Federal laws.

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

(d) Narcotic Permit. Each ESRD and/or Renal Transplant 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 professional nurse, a physician’s assistant or a physician and shall be entered on the physician's order sheet with an indication as to the prescribing physician, certified registered nurse practitioner or physician assistant and who wrote the order. Telephone or oral orders shall be signed by the prescribing individual within fifteen days.

(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 medicines, and avoid

overcrowding of preparation and handling areas. The pharmacy shall comply with all State and Federal Regulations governing the operation of a pharmacy. In addition, the pharmacy shall also:

1. Be adequately lighted.

2. Be provided with proper safeguards.

3. Be provided with a counter and sink.

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) Drug Reference Sources. Each End Stage Renal Treatment and Transplant Center shall maintain reference sources for identifying and prescribing drugs and medicines.

(j) Pharmacist. The facility shall maintain in a prominent location the name and telephone number of registered pharmacist who shall be available to offer advice on the maintenance and use of medicines and drugs, and to offer input into the care planning of the patient.

(k) Safety. If the pharmacies and/or drug rooms are available, they shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors.

(5) Dietetic Services.

(a) Qualified Dietitian. There is a qualified dietitian employed by the facility or contracted by the facility who is responsible, in consultation with the attending physician, for assessing the patient's nutritional and dietetic needs, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring patient response.

(b) Self-Care Dialysis Support Service. If the facility furnishes self-care dialysis training after the patient has completed a training program, the facility or center provides

the services of a dietitian, either directly or under arrangement.

(6) Social Services.

(a) Social Worker. The facility has a qualified social worker, either employed by the facility, or on a contractual basis, for conducting psychosocial evaluations, participating on professional team review of patient care, providing casework and group work for patients and their families and identifying helpful community resources and assisting patients and their families to use them.

(b) Self-Care Dialysis Support Service. If the facility or center furnishes self-care dialysis training after the patient has completed a training program, the facility or center provides the services of a social worker either directly or under agreement.

(7) Laboratory.

(a) Laboratory Requirements.

1. Patient required laboratory services are available either directly or under arrangements through a hospital laboratory or a licensed independent laboratory.

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 those 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).

3. Staff qualified by education and experience may perform hematocrit and clotting time tests within the unit under the direction of a physician as outlined in Rule 420-5-8-.04(4) and (5), Chapter 420-5-8, Independent Clinical Laboratories, Alabama Administrative Code. Evidence of education, training, and experience shall be maintained in the personnel record.

4. If the facility has its own laboratory, it shall be in full compliance with Chapter 420-5-8, Independent Clinical Laboratories, Alabama Administrative Code including all amendments.

(b) Physician Orders. There shall be a written physician's order for laboratory procedures performed.

(c) Laboratory Reports. Completed reports of laboratory tests shall be kept on file with the patient's chart. Such reports

shall be signed, initialed or coded to indicate the individual(s) by whom they were performed. There shall be evidence that the results of laboratory reports have been reported to the physician.

(d) Safety Measures. Procedures shall be established and enforced for the safe handling of all potentially infectious specimens and for the disposal or terminal disinfection of such material, supplies or equipment.

**Author:** Rick Harris
**Statutory Authority:** Code of Ala. 1975, §§22-21-20, et seq.
**History:** Filed September 30, 1982. **Amended:** Filed November 19, 1987. **Amended:** Filed September 20, 2001; effective October 25, 2001. **Amended:** Filed June 23, 2004; effective July 28, 2004. **Amended:** Filed November 13, 2007; effective December 18, 2007.

**420-5-5-.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 Standard Building Code*, and shall comply with the codes and standards adopted by the State Board of Health at the time of plan submission.

(b) New Construction, Additions, and Major Alterations. When construction is contemplated, either for new buildings, 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."

(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 dialysis and/or transplant facility is licensed, need not be submitted for approval.

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

(2) General.

(a) Location. The facility shall provided sufficient parking space for patients, visitors and staff. The facility and its

services shall be accessible to disabled individuals as required by federal law.

(b) Local Restrictions. The dialysis 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.

(e) Ventilation. The building shall be well ventilated at all times with a comfortable temperature maintained. Portable and window air circulating fans are prohibited.

(f) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of all waste. Infectious and potential waste material shall be rendered non-infectious on the premises either by autoclaving, incineration or immersion in formaldehyde, or shall be delivered by employees of the ESRD Facility directly to an incinerator. In the latter case, the ESRD Facility must complete an Agreement with the owner of said incinerator delineating appropriate measures for the proper disposal of such waste. During transportation, such waste must be labeled, placed in double bags and sharp objects placed within rigid-walled containers. Removal of such waste shall not be through patient use areas.

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

(h) Doors. All doors to Treatment Rooms and Patient Use Areas shall be no less than 36 inches wide.

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

(j) Corridors. Corridors required for exit access shall be as a minimum 5 feet wide.

(k) Occupancy. No part of a dialysis 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) Exit Doors. Exit doors shall meet the following criteria:

1. Shall be no less than 36 inches wide.

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

(n) Floors. All floors in treatment areas shall be smooth resilient tile or seamless flooring, 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.

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

(p) Handicap Facilities. The facility shall be accessible to the physically handicapped and shall comply with *ADA Accessibility Guidelines*.

(q) Reuse Rooms. Reuse Rooms shall be separated from the rest of the facility by one hour fire resistive construction. Rooms shall be of adequate size and design to prevent co-mingling of dirty and clean dializers. Ventilation for Reuse rooms shall comply with AAMI requirements.

(3) Service Facilities.

(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.

(b) Preventive Maintenance. There shall be a preventive maintenance program to ensure that all mechanical, electrical and patient care equipment is maintained in safe operating condition. Also, records shall be maintained as to the calibration and maintenance of equipment in accordance with the manufacturers recommendation. Cleaning of dialysis equipment shall be carried out with appropriate disinfecting agents. Air-conditioning and heating filters must be inspected monthly to ensure and maintain their effectiveness. Filter inspections shall be recorded.

(c) Dialysis Station. The treatment area shall contain a minimum of 70 square feet per dialysis station and be so arranged as to facilitate both routine and emergency care of the patient, and emergency evacuation.

(d) Waiting Room. A waiting room in the administrative section shall be provided with sufficient seating for the maximum number of persons that may be present at any time. Waiting room shall be separated from the Treatment Area by a wall and door with locking capability. Public toilet(s) shall be available in the waiting room.

(e) Storage Facilities. Storage rooms will be provided in order that ample space be available for storage of supplies and equipment. Storage Rooms of more than 50 square feet in area shall be enclosed with one hour fire rated construction, with 45 minute fire rated, self closing doors.

**Author:** Tigner Zorn, L. O'Neal Green, Cecil Barnes, Victor Hunt
**Statutory Authority:** Code of Ala. 1975, §§22-21-20, et. seq.
**History:** Filed September 1, 1982. **Amended:** Filed December 19, 1986; November 20, 1992. **Amended:** Filed February 20, 1997; effective March 27, 1997. **Amended:** Filed September 20, 2001; effective October 25, 2001. **Amended:** Filed June 18, 2002; effective July 23, 2002. **Amended:** Filed August 22, 2005; effective September 26, 2005.

**420-5-5-A** **Appendix A.**

**CODE OF ALA. 1975, SECTIONS 22-21-20, ET SEQ.**

**§22-21-20. Definitions.** For the purpose of this article, the following terms shall have the meanings respectively ascribed to them by this section:

(1) HOSPITALS. General and specialized hospitals, including ancillary services; independent clinical laboratories; rehabilitation centers; ambulatory surgical treatment facilities for patients not requiring hospitalization; end stage renal disease treatment and transplant centers, including free-standing hemodialysis units; abortion or reproductive health centers; hospices; health maintenance organizations; and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis and/or treatment of injury, deformity, disease, surgical or obstetrical care. Also included within the term are long term care facilities such as, but not limited to, skilled nursing facilities, intermediate care facilities, homes for the aged, domiciliary care facilities and related health care institutions when such institution is primarily engaged in offering room, board, laundry and personal assistance with activities of daily living and incidentals thereto. The term "hospitals" relates to health care institutions and shall not include the private offices of physicians or dentists, whether in individual, group, professional corporation or professional association practice. This section shall not apply to county or district health departments.

(2) PERSON. Such term includes individuals, partnerships, corporations and associations. (Acts 1975, 3rd Ex. Sess., No. 140, p. 382, §1; Acts 1979, No. 79-798, p. 1461; Acts 1991, No. 91-548, p. 1010, §1; Act 1997, No. 97-632, §1.)

**§22-21-21. Purpose of article.** The purpose of this article is to promote the public health, safety and welfare by providing for the development, establishment and enforcement of standards for the treatment and care of individuals in institutions within the purview of this article and the establishment, construction, maintenance and operation of such institutions which will promote safe and adequate treatment and care of individuals in such institutions. (Acts 1949, No. 530, p. 835, §1; Acts 1962, Ex. Sess., No. 122, p. 157, §1.)

**§22-21-22. License -- Required; exceptions.** No person shall establish, conduct or maintain any hospital as defined in Section 22-21-20 without first obtaining the license provided in this article. Hospitals operated by the federal government and mental hospitals under the supervision of the board of trustees of the Alabama State Hospitals shall be exempt from the provisions of

this article. (Acts 1949, No. 530, p. 835, §2; Acts 1962, Ex. Sess., No. 122, p. 157, §2.)

**§22-21-23. License -- Application.** Any person desiring licensing under this article shall apply to the State Board of Health therefore. The applicant shall state the name of the applicant and whether an individual, partnership, corporation or other entity, the type of institution for which a license is desired, the location thereof and the name of the person in direct supervision and charge thereof. The person in charge of such hospital must be at least 19 years of age, of reputable and responsible character and in sound physical and mental health. Like evidence of fitness shall be submitted when required, except for age, as to those individuals employed at, or in, such hospital in a supervisory capacity. The applicant shall likewise submit evidence of ability to comply with the minimum standards provided in this article or by regulations issued under its authority. (Acts 1949, No. 530, p. 835, §4.)

**§22-21-24. License -- Fees; term; form; nontransferable; posting; renewal; hospital licensable when accredited by joint commission.** The application for a license to operate a hospital shall be accompanied by a standard fee of $200.00, plus a fee of $5.00 per bed for each bed over 10 beds to be licensed in accordance with regulations promulgated under Section 22-21-28. Increase in a hospital's bed capacity during the calendar year is assessed at the standard fee of $200.00 plus $5.00 each for the net gain in beds. No fee shall be refunded. All fees received by the State Board of Health under the provision of this article shall be paid into the State Treasury to the credit of the State Board of Health and shall be used for carrying out the provisions of this article. All licenses issued under this article shall expire on December 31 of the year in which it was issued. All licenses shall be on a form prescribed by said department, shall not be transferable or assignable, shall be issued only for the premises named in the application, shall be posted in a conspicuous place on the licensed premises and may be renewed from year to year upon application, investigation and payment of the required license fee, as in the case of procurement of the original license. All fees collected under this article are hereby appropriated for expenditure by the State Health Department. All hospitals which are accredited by the joint commission on accreditation of hospitals shall be deemed by the State Health Department to be licensable without further inspection or survey by the personnel of the State Department of Health. Further accreditation by the joint commission on accreditation of hospitals shall in no way relieve that hospital of the responsibility of applying for licensure and remitting the appropriate licensure fee as specified in this article. (Acts 1949, No. 530, p. 835, §5; Acts 1975, 3rd Ex. Sess., No. 140, p. 382, §2; Acts 1980, No. 80-642, p. 1213; Acts 1988, 1st Ex. Sess., No. 88-902, p. 470.)

**§22-21-25. License -- Issuance; suspension or revocation; new applications after revocation.**

(a) The State Board of Health is hereby authorized to issue licenses for the operation of hospitals which are found to comply with the provisions of this article and any regulations lawfully promulgated by the said State Board of Health.

(b) The State Board of Health is hereby authorized to suspend or revoke a license issued under this article on any of the following grounds:

(1) Violation of any of the provisions of this article or the rules and regulations issued pursuant thereto;

(2) Permitting, aiding or abetting the commission of any illegal act in such institution; or

(3) Conduct or practices deemed by the State Board of Health to be detrimental to the welfare of the patients of said institution.

(c) Before any such license issued under this article is suspended or revoked, written notice shall be given the licensee, stating the grounds of the complaint, and the date, time and place set for the hearing of said complaint, which date of hearing shall be not less than 30 days from the date of the notice. Such a notice shall be sent by registered or certified mail to the licensee at the address where the institution concerned is located. The licensee shall be entitled to be represented by legal counsel at the hearing.

(d) If a license is revoked as provided in this section, a new application for license shall be considered by the State Board of Health if, when and after the conditions upon which revocation was based have been corrected and evidence of this fact has been furnished. A new license shall then be granted after proper inspection has been made and all provisions of this article and rules and regulations promulgated under this article have been satisfied. (Acts 1949, No. 530, p. 835, §7.)

**§22-21-26. License -- Judicial review of suspension or revocation.** Any party aggrieved by a final decision or order of the Board of Health suspending or revoking a license is entitled to a review of such decision or order by taking an appeal to the circuit court of the county in which the hospital is located or is to be located. (Acts 1949, No. 530, p. 835, §11.)

**§22-21-27. Advisory board.**

(a) There shall be an advisory board of 12 members to assist in the establishment of rules, regulations and standards necessary to carry out the provisions of this article and to

serve as consultants to the State Health Officer. The board shall meet at least twice each year and at the call of the State Health Officer. The members of the board shall annually elect one of its members to serve as chairman.

(b) The advisory board shall be constituted in the following manner:

(1) Four representatives of hospitals, who shall be appointed by the Board of Trustees of the Alabama Hospital Association as follows:

a. One administrator of a governmental hospital;

b. One administrator of a nongovernmental nonprofit hospital;

c. One owner or administrator of a proprietary hospital; and

d. One member of a managing board of a nonprofit hospital;

(2) Three representatives who shall be doctors of medicine appointed by the Board of Censors of the Alabama State Medical Association;

(3) One representative who shall be a registered nurse appointed by the executive board of the Alabama State Nurses Association;

(4) One representative from the State Board of Human Resources to be appointed by the board;

(5) One registered pharmacist actively engaged in the practices of pharmacy in the State of Alabama, to be appointed by the Alabama State Board of Pharmacy;

(6) One member of the advisory board shall be appointed by the executive committee of the Alabama Nursing Home Association, who shall be the operator of a duly qualified licensed nursing home; and

(7) One member shall be appointed by the Alabama Hospice Association and said person shall vote only on issues relating to hospices.

Of the original representatives appointed by the Board of Trustees of the Alabama Hospital Association, one shall serve for three years, two shall serve for four years, and one shall serve for five years. One of the representatives appointed by the Board of Censors of the Alabama State Medical Association shall serve for two years, one shall serve for three years,

and one shall serve for five years. The one representative appointed by the Alabama State Nurses Association shall serve for four years. The one representative from the State Board of Human Resources shall serve for four years, and the one representative from the State Board of Pharmacy shall serve for four years. The representative appointed by the executive committee of the Alabama Nursing Home Association shall serve for five years. Thereafter, each new appointee shall serve for five years or until his successor is appointed; except, that in the case of a vacancy, the appointee shall serve for the remainder of the unexpired term. Any vacancy shall be filled by the original organization selecting said member.

(c) Members of the advisory board shall not be eligible to succeed themselves after they have served one full five-year term, but shall be eligible for reappointment if they have not served immediately preceding their reappointment.

(d) Members of the advisory board shall serve without compensation, but shall be entitled to reimbursement for expenses incurred in the performance of the duties of their office pursuant to Article 2 of Chapter 7 of Title 36. (Acts 1949, No. 530, p. 835, §9; Acts 1959, No. 134, p. 656; Acts 1991, No. 91-548, p. 1010, §1.)

**§22-21-28. Rules and regulations.**

(a) In the manner provided in this section, the State Board of Health, with the advice and after approval by the advisory board, shall have the power to make and enforce, and may modify, amend and rescind, reasonable rules and regulations governing the operation and conduct of hospitals as defined in Section 22-21-20. All such regulations shall set uniform minimum standards applicable alike to all hospitals of like kind and purpose in view of the type of institutional care being offered there and shall be confined to setting minimum standards of sanitation and equipment found to be necessary and prohibiting conduct and practices inimicable to the public interest and the public health. The board shall not have power to promulgate any regulation in conflict with law nor power to interfere with the internal government and operation of any hospital on matters of policy. Thirty days notice of any proposed amendment, rescission or new regulations shall be given in writing to all licensed hospitals of the date of such hearing and of the substance of any new regulation, amendment to or rescission of regulation proposed to be made. All hearings shall be joint hearings set by the Board of Health and the advisory board established in Section 22-21-27 at Montgomery, Alabama. At such hearing, any interested hospital or any member of the public may be heard.

(b) Any person affected by any regulation, amendment or rescission thereof may appeal consideration thereof to the

circuit court of the county of that person's residence or in which that person does business or to the Circuit Court of Montgomery County, within 30 days from the adoption of the same following the hearing provided in this section by giving security for costs and the filing of a petition with court, setting forth the interest of the appellant, the ruling complained of and the facts upon which the petitioner relies for relief. And upon appeal the question of the reasonableness of such regulation shall be a question of fact for the court to determine, and no presumption shall be indulged that the regulation adopted was and is a reasonable regulation.

(c) Regulations adopted under this section shall become effective upon the expiration of 30 days from the date of adoption, amendment or rescission or, if an appeal has been taken, upon the final disposition of the appeal. From any judgment of the circuit court in any case appealed to it, an appeal shall lie to the court of civil appeals of Alabama within 42 days from the date of entry of the judgment, in the same manner as other appeals are now authorized by law, and no presumption shall be indulged by the court of civil appeals as to the correctness of the trial court's finding of facts. (Acts 1949, No. 530, p. 835, §8.)

**§22-21-29. Inspections.**

(a) Every hospital licensed under this article shall be open to inspection to the extent authorized in this section by the State Board of Health, under rules as shall be promulgated by the board with the advice and consent of the advisory board. Nothing in this section shall authorize the board to inspect quarters therein occupied by members of any religious group or nurses engaged in work in such hospital or places of refuge for members of religious orders for whom care is provided, but any inspection shall be limited and confined to the parts and portions of such hospital as are used for the care and treatment of the patients and the general facilities for their care and treatment. No hospital shall, by reason of this section, be relieved from any other types of inspections authorized by law.

(b) All inspections undertaken by the State Board of Health shall be conducted without prior notice to the facility and its staff. Notwithstanding the foregoing, an inspection of a hospital or other health care facility, prior to its licensure, may be scheduled in advance. An employee or contract employee of the state shall not disclose in advance the date or the time of an inspection of a hospital or other health care facility to any person with a financial interest in any licensed health care facility, to any employee or agent of a licensed health care facility, to any consultant or contractor who performs services for or on behalf of licensed health care facilities, or to any person related by blood or

marriage to an owner, employee, agent, consultant, or contractor of a licensed health care facility. For purposes of this section, the term inspection shall include periodic and follow-up compliance inspections and surveys on behalf of the State Board of Health, complaint investigations and follow-up investigations conducted by the State Board of Health, and compliance inspections and surveys, complaint investigations, and follow-up visits conducted on behalf of the United States Department of Health and Human Services, Health Care Financing Administration, or its successors. The board may prescribe by rule exceptions to the prohibition where considerations of public health or safety make advance disclosure of inspection dates or times reasonable. Disclosure in advance of inspection dates when such disclosure is required or authorized pursuant to federal law or regulation shall not be a violation of this section. Scheduling inspections of hospitals or other health care facilities by the board at regular, periodic intervals which may be predictable shall not be a violation of this section.

(c) Any employee or contract employee of the state who discloses in advance the date or time of an inspection in violation of subsection (b) shall be guilty of a Class A misdemeanor. Any person who solicits an employee or contract employee of the state to disclose in advance the date or time of an inspection in violation of subsection (b) for the purpose of disclosing the information to others shall be guilty of a Class A misdemeanor. (Acts 1949, No. 530, p. 835, §6; Act 1997, No. 97-632, §1.)

**§22-21-30. Disclosure of information.** Information received by the State Board of Health through on-site inspections conducted by the State Licensing Agency is subject to public disclosure and may be disclosed upon written request. Information received through means other than inspection will be treated as confidential and shall not be directed publicly except in a proceeding involving the question of licensure or revocation of license. (Acts 1949, No. 530, p. 835, §10; Acts 1975, 3rd Ex. Sess., No. 140, p. 383, §3.)

**§22-21-31. Practice of medicine, etc., not authorized; child-placing.** Nothing in this article shall be construed as authorizing any person to engage in any manner in the practice of medicine or any other profession nor to authorize any person to engage in the business of child-placing. Any child born in any such institution whose mother is unable to care for such child or any child who, for any reason, will be left destitute of parental support shall be reported to the State Department of Health and Human Resources or to any agency authorized or licensed by the State Department of Health and Human Resources to engage in child placing for such service as the child and the mother may require. In the rendering of such service, representatives of the State Department of Health and Human Resources and agencies authorized or licensed by the State Department of Health and Human Resources shall have free

access to visit the child and the mother concerned. (Acts 1949, No. 530, p. 835, §2; Acts 1962, Ex. Sess., No. 122, p. 157, §2.)

**§22-21-32.** Repealed by Acts 1977, 1st Ex. Sess., No. 82, p. 1509, §19, effective June 16, 1977.

**§22-21-33. Penalty for violation of article, etc.** Any individual establishing, conducting, managing or operating a hospital without first obtaining a license therefore as provided in this article or who shall violate any of the provisions of this article, or regulations promulgated thereunder, shall be guilty of a misdemeanor and, upon conviction, shall be punished by a fine of not to exceed $100.00 or by imprisonment in the county jail for a period not to exceed 90 days, or by both such fine and imprisonment in the discretion of the court. Any association, corporation or partnership operating a hospital in violation of any provisions of this article, or any regulation promulgated thereunder, shall be subject to the payment of a penalty of $25.00 per day for each day of such illegal operation, which may be recovered by the State Board of Health in an appropriate civil action. The State Board of Health may, upon the advice of the Attorney General, maintain an action in the name of the state for an injunction to restrain any state, county or local governmental unit, or any division, department, board or agency thereof, from operating, conducting or managing a hospital in violation of any provisions of this article, or any regulation promulgated thereunder. (Acts 1949, No. 530, p. 835, §12.)
**Author:**
**Statutory Authority:**
**History:**