RULES
OF
ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH

CHAPTER 420-5-8

INDEPENDENT CLINICAL LABORATORIES AND
INDEPENDENT PHYSIOLOGICAL LABORATORIES

With Licensure Law

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STATE OF ALABAMA
DEPARTMENT OF PUBLIC HEALTH
MONTGOMERY, ALABAMA
CHAPTER 420-5-8

INDEPENDENT CLINICAL LABORATORIES AND INDEPENDENT PHYSIOLOGICAL LABORATORIES

TABLE OF CONTENTS

420-5-8.01 General ........................................................................................................1
420-5-8.02 The License .................................................................................................5
420-5-8.03 Personnel Qualifications .........................................................................7
420-5-8.04 Management ..............................................................................................11
420-5-8.05 Specific Requirements for Independent Physiological Labs ........18
420-5-8.06 Building Requirements ...........................................................................21
420-5-8.01 General.

(1) **Legal Authority for Adoption of Rules.** Under and by virtue of authority vested in it by the Legislature of Alabama, *Code of Alabama 1975*, Section 22-21-20, et seq., requiring independent clinical laboratories and health care institutions engaged in offering diagnostic services to be licensed by the Alabama State Board of Health, the State Board of Health does hereby adopt and promulgate the following Rules governing all independent clinical laboratories and all independent physiological laboratories and other related institutions in Alabama, except those operated under the supervision of the Department of Mental Health and those laboratories otherwise exempt by law from licensure. Sections 420-5-8.01, 420-5-8.02, 420-5-8.05, and 420-5-8.06 are applicable to independent physiological laboratories. All sections of these Rules, except section 420-5-8.05 are applicable to independent clinical laboratories.

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

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

(b) "Accredited" means accreditation by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education or the Alabama Department of Public Health.

(c) "Advisory Board." See Section 22-21-27 of the Appendix to these Rules.

(d) "Biophysical Procedures" means procedures wherein specimens which have been removed from the human body are subjected to biophysical determinations.

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

(f) "Collection Station" means a facility where materials or specimens are withdrawn or collected from patients for subsequent delivery to a clinical laboratory for examination. Physicians' offices are exempted from this definition.

(g) "Director" means any qualified person responsible for administration of technical and scientific operations of a laboratory, including supervision of testing procedures and result reporting.

(h) "Independent Clinical Laboratory" means any laboratory which operates primarily independent of other health care facilities that are licensed by the Alabama State Board of Health, or hospital laboratories that receive and perform reference work from sources outside of the hospital, and
performs diagnostic and medical laboratory procedures upon referral. Independent clinical laboratory shall include laboratories operated by blood banks, plasmapheresis banks, radioisotope facilities, specimen collection stations, and laboratories engaged in manufacturing diagnostic test reagents from human whole blood or whole blood derivatives. Federal and State laboratories shall be excluded from these Rules.

(i) "Independent Physiological Laboratory" means any facility or unit, mobile or otherwise, that provides diagnostic physiological services for humans, for example, pulmonary function tests, spirometer, EKG, Holter monitor, EEG, transtelephonic pacemaker analysis, oximetry, diagnostic hearing tests, echo-ultrasound, diagnostic ultra sound, doppler studies, and non-invasive peripheral vascular studies. Facilities that provide ionizing radiation or magnetic resonance imaging only are excluded from this definition. Private physician offices performing diagnostic physiological services exclusively for their patients are excluded from this definition.

(j) "License" means the document issued by the State Board of Health and signed by the State Health Officer. The license shall constitute the authority to receive patients and perform the services included within the scope of these Rules.

(k) "Licensee" means the corporate body or individual to whom the license is issued and upon whom rests the responsibility for compliance with these Rules.

(l) "Licensed Practitioner of the Healing Arts" means a person currently licensed to practice medicine and surgery in the State of Alabama.

(m) "May" indicates permission.

(n) “Mobile Unit” means a laboratory testing unit, either independent clinical or independent physiological, that moves from testing site to testing site, or has a temporary testing location. The mobile unit shall provide the State Board of Health with an Alabama permanent address and an address of the physical location of the home base. The mobile unit must submit to the Board a monthly schedule of hours of operation and of the locations the mobile unit will be performing the procedures.

(o) "Patient" means a person referred to the independent clinical laboratory by and upon the recommendation of a physician.

(p) "Physician" means a person currently licensed to practice medicine in Alabama under the provisions contained in current state statutes.
(q) "Plasmapheresis and Whole Blood Centers" mean facilities which provide a system for collection, processing or storage of human blood and/or its components. Plasmapheresis and whole blood donor centers operating within this state shall obtain a license from the Alabama Department of Public Health. Such plasmapheresis and whole blood donor centers shall be maintained in accordance with the AAC Rule 420-5-8.02, 420-5-8.03(1)(a)(1), 420-5-8.04(1)(a), 420-5-8.04(4), 420-5-8.04(5)(c), and 420-5-8.06.

(r) "Qualifying Adjectives," such as adequate, proper, safe, sufficient, satisfactory, suitable, and substantial mean the degree of propriety or compliance that is being maintained by other independent clinical laboratories in Alabama that currently hold a regular license issued by the State Board of Health.

(s) "Shall" indicates mandatory requirements.

(t) "Supervisor" means any qualified person who, under general supervision of a director, supervises technical personnel, performs tests requiring special scientific skills, and in the absence of the director, is held responsible for proper performance of all laboratory procedures and the reporting of results.

(u) "Technician" means any qualified person who functions under the direct supervision of a director, supervisor, or technologist and performs only those clinical laboratory procedures which require limited skill, responsibility, and a minimal exercise of independent judgment.

(v) "Technologist" means any qualified person who performs tests which require the exercise of independent judgment and responsibility with supervision by the director or supervisor, in only those specialties or subspecialties in which the person is qualified by education, training, and experience.

(w) "These Rules" means Rules 420-5-8.01 through 420-5-8.06, Chapter 420-5-8, Independent Clinical Laboratories, Alabama Administrative Code.

(x) "Trainee" means any person who is employed to perform services with or without remuneration or for the direct or indirect benefit of a clinical laboratory or owner and is being trained for the category for which he has applied.
(3) **Procedures Governing Adoption, Amendment, and Revision of Rules.**

(a) **Authority.** The State Board of Health, with the advice and approval of the Advisory Board defined in *Code of Alabama*, 1975, Section 22-21-27, has the legal authority to adopt reasonable rules governing the operation and conduct of independent clinical laboratories and independent physiological laboratories, and it may amend or rescind any rules previously adopted.

(b) **Joint Hearings.** All hearings shall be joint hearings set by the State Board of Health and the Advisory Board, at which time any interested member of the public may be heard.

(c) **Procedures.** In adopting, amending, or rescinding rules, the Board shall follow the provisions of the Alabama Administrative Procedure Act. The effective date of any rules adopted, amended or rescinded shall likewise be governed by the Administrative Procedure Act.

(4) **Inspection.**

(a) **Inspections Required.** Each independent clinical laboratory or independent physiological laboratory for which a license has been granted may be inspected by the State Board of Health, or by its authorized representatives at such intervals as the Board may direct.

(b) **Information Shall Be Confidential.** Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections, and plans of correction 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 affected facility’s license or proceedings involving the license of another facility operated by the same governing authority.

**Author:** L. O’Neal Green, Patricia E. Ivie, Rick Harris  
**Statutory Authority:** *Code of Alabama* 1975, 22-21-20, et seq.  
420-5-8.02 The License.

(1) Types of License.

(a) Regular License. A regular license may be issued by the State Board of Health after the board has determined that the independent clinical or physiological laboratory is in substantial compliance with the Rules herein adopted.

(b) Probational license. The State Board of Health may, in its discretion and in lieu of license revocation, issue a probational license to a facility when inspection shows that the maintenance and operation of the facility are such that the independent clinical laboratory or independent physiological laboratory no longer substantially complies with the rules adopted herein. However, the Board may issue a probational license only after determining that the health and safety of patients are adequately protected despite non-compliance, and that the facility has submitted an adequate written plan to correct the non-compliance in a timely manner. Maximum length of time for probational status is one year.

(c) Downgrade or Revocation of License. The State Board of Health is authorized to downgrade or revoke a license for any of the following reasons:

1. Violation of any of the provisions of these Rules.

2. Permitting, aiding or abetting the commission of any illegal act in such institution.

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

(2) Application.

(a) Application. An application for license or renewal of license shall be made on forms provided by the State Board of Health and shall contain such information as the Board may require.

(b) Fee. Each application for license shall be accompanied by a fee as mandated by statute. No fee shall be refunded. Fees shall be paid by cash, check or money order made payable to the Alabama Department of Public Health.
(3) **Licensing.**

(a) **Issuance of License.** The license shall be issued by the State Board of Health. It shall set forth the name and physical location in Alabama of the independent clinical laboratory or independent physiological laboratory.

(b) **Separate Licenses.** A separate license shall be required for each independent clinical laboratory or independent physiological laboratory when more than one independent clinical laboratory or independent physiological laboratory is operated under the same management; however, separate licenses are not required for separate buildings on the same grounds used by the same independent clinical laboratory or independent physiological laboratory.

(4) **Right of Review.** Whenever a license is denied or revoked, the applicant or licensee will be afforded an opportunity for a hearing in accordance with the requirements for contested case proceedings under the Alabama Administrative Procedures Act, Code of Alabama 1975, § 41-22-17, and Chapter 420-1-3 of the Alabama Administrative Code.

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

(b) **Reissuing of License.** See Section 22-21-25 of Appendix.

(5) **Disclosure of Information.** Disclosure of Information received by State Board of Health. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections, and plans of correction 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 affected facility’s license or proceedings involving the license of another facility operated by the same governing authority.

**Author:** L. O’Neal Green, Rick Harris

**Statutory Authority:** *Code of Alabama 1975*, 22-21-20, et seq.

420-5-8.03 Personnel Qualifications.

(1) Director.

(a) A director shall meet one of the following requirements:

1. Is a physician licensed to practice medicine in Alabama with at least two years of pertinent laboratory experience.

2. Holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject, and

   (i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, or other national accrediting boards with equivalent standards accepted by the State Health Department in one of the laboratory specialties and may direct only that division or subspecialty for which he is certified, or

   (ii) Has four or more years of general clinical laboratory training and experience, of which at least two years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory, under a director at the doctoral level, of a hospital, a health department, a university or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health.

(2) Supervisor.

(a) A supervisor shall meet one of the following requirements:

1. Is a physician licensed to practice medicine in Alabama and has had at least two years of pertinent laboratory experience; or

2. Has earned a doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and has had at least two years experience in one of the laboratory specialties in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

3. Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and has had
at least four years of pertinent laboratory experience of which not less than two years has been spent working in one of the laboratory specialties in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

4. Holds a bachelor's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and has had at least six years of pertinent laboratory experience of which not less than two years has been spent working in one of the laboratory specialties in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

5. Successful completion of three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university with a chemical, physical, or biological science as a major subject and meets the requirements of a technologist under AAC Rule 420-5-8.03(3) and has at least six years of experience in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health.

6. Achieve a satisfactory grade on a proficiency examination for technologists approved by the United States Secretary of Health and Human Services and have six years of full-time laboratory experience obtained after passing the examination.

(b) An exception in AAC Rule 420-5-8.03(2) may be made when emergencies arise outside regularly scheduled hours of duty, an individual who qualifies as a supervisor is not required to be on the premises provided that the technologist performing tests is qualified to perform such tests, the supervisor who is responsible for the results of the work reviews them during the next duty period, and a record is maintained to reflect the actual review.

(3) **Technologist.**

(a) A technologist shall meet one of the following requirements:
1. Successful completion of a full course of study which meets academic requirements for a bachelor's degree in medical technology from an accredited college or university; or

2. Successful completion of three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university which meets the requirements for entrance into and the successful completion of a course of training of at least 12 months in a school of medical technology approved by the Council on Medical Education and Hospitals of the American Medical Association; or

3. Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical, or biological sciences and at least one year of pertinent laboratory experience or training covering the specialties or subspecialties in which tests are performed, provided the combination has given the individual the equivalent in those specialties or subspecialties of the education and training described in AAC Rule 420-5-8.03(3)(a)1, and 2.

4. Successful completion of three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university with a chemical, physical, or biological science as a major subject and at least one year of experience in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

5. Achieve a satisfactory grade on a proficiency examination approved by the United States Secretary of Health and Human Services.

(4) Technician.

(a) A technician shall meet one of the following requirements:

1. Successful completion of two years of academic study (a minimum of 60 semester hours or equivalent) in an accredited college or university and have an associate's degree in Medical Technology; or

2. Graduation from high school and subsequent to graduation has had two years of experience as a technician trainee in a clinical
laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

3. Graduation from high school and successful completion of an official military laboratory procedures course of at least 12 calendar months of study and has had at least one year of experience as a technician trainee in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health.

(b) No clinical laboratory technician performs procedures in the absence of a qualified clinical laboratory technologist, supervisor, or director.

(5) Supervisor, Cytotechnologist. If the laboratory performs only anatomical procedures, a cytotechnologist meeting qualifications under AAC Rule 420-5-8.03(6) and having four years of experience as a cytotechnologist may supervise other cytotechnologists and histotechnicians.

(6) Cytotechnologist.

(a) Cytotechnologists shall meet one of the following requirements:

1. Has successfully completed two years in an accredited college or university with at least 12 semester hours in science, 8 hours in biology, and

   (i) has had 12 months of training in a school of cytotechnology accredited by an accrediting agency and approved by the State, or

   (ii) has received six months of formal training in a school of cytotechnology accredited by an accrediting agency and six months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal six months of training, or

2. Prior to January 1, 1969, has:

   (i) been graduated from high school,
Independent Clinical Laboratories
and Independent Physiological Laboratories

Chapter 420-5-8

(ii) completed six months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and

(iii) completed two years of full-time supervised experience in cytotechnology, or

3. Achieved a satisfactory grade in a proficiency examination approved by the United States Secretary of Health and Human Services; however, after December 31, 1977, initial certification as a cytotechnologist must be in accordance with AAC Rule 420-5-8.03(6)(a)1, or 2.

(7) Technician Trainee.

(a) A "technician trainee" shall mean an employee who is a high school graduate or equivalent, who is gaining the required two years of clinical laboratory on-the-job experience to qualify as a technician, and who is participating in a structured training program approved by the State Health Department and designed to provide the trainee with a broad range of laboratory procedures of progressive technical difficulty.

(b) A technician trainee performs only repetitive procedures which require a minimal exercise of independent judgment and may perform such procedures only under the personal and direct supervision of a qualified supervisor or technologist.

Author: L. O’Neal Green, Rick Harris.

420-5-8.04 Management.

(1) Personnel.

(a) The laboratory shall be under the direction of a director and shall provide the number of other qualified personnel commensurate with the volume and type of tests performed.

(b) The laboratory shall perform only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director, supervisors, or persons engaged to perform tests are qualified.
(c) The laboratory may perform laboratory procedures and tests in all specialties provided that the director or supervisor is a pathologist certified or eligible for certification in both anatomical and clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology.

(d) In circumstances where AAC Rule 420-5-8.04(1)(c) is not met, the following criteria shall be used to establish qualifications of laboratory personnel to perform each specialty:

1. Microbiology, including serology - The laboratory engages the services of an individual who holds an earned doctoral degree or master's degree in microbiology from an accredited institution or is a licensed practitioner of the healing arts with two years of experience in microbiology.

2. Hematology - The laboratory engages the services of an individual who holds a master's or bachelor's degree in biology, immunology or microbiology from an accredited institution and has had at least four years experience in hematology or is a licensed practitioner of the healing arts with pertinent experience.

3. Immunohematology - The laboratory engages the services of a licensed physician with specific experience in this field or an individual with a master's or bachelor's degree in biology, immunology or microbiology from an accredited institution and has four years of experience in immunohematology.

4. Chemistry - The laboratory engages the services of an individual who holds an earned doctoral degree or master's degree in chemistry or biochemistry from an accredited institution or is a licensed practitioner of the healing arts with two years experience in clinical chemistry.

5. Histopathology - The laboratory engages the services of a licensed practitioner in the healing arts who is certified in anatomic pathology or is eligible for certification by the American Board of Pathology or the American Board of Osteopathic Pathology or possesses qualifications which are equivalent to those required for certification by these Boards.

6. Cytotechnology - The laboratory engages the services of a licensed practitioner of the healing arts who is certified in anatomic pathology or is eligible for certification by the American Board of Pathology or the American Osteopathic Board of Pathology or is
certified by the American Society of Cytology to practice cytopathology or who possesses qualifications which are equivalent to those required for certification by these Boards.

(2) **Operation.**

(a) Equipment shall be provided and maintained for the proper performance of the specialties and volume of service offered.

(b) The laboratory shall be in compliance with all state and local laws and regulations including those relating to construction and sanitary conditions and also including the handling and disposal of specimens.

(3) **Administration and Organization.**

(a) The director shall serve the laboratory full time or on a regular part-time basis and shall be readily available for personal or telephone consultations.

(b) If the director is not in attendance throughout normal periods of operation, at least one clinical laboratory supervisor shall be available and on the premises.

(c) The licensee shall be responsible for the proper maintenance and conduct of the laboratory.

(4) **Procedures and Equipment.**

(a) All technical procedures employed in the laboratory shall be the standard procedures which are generally accepted by leading authorities in microbiology, serology, chemistry, hematology, immunohematology, biophysics, cytotechnology, and histopathology as applicable or are equivalents approved by the Alabama Department of Public Health.

(b) There shall be quality control procedures in effect, including the use of reference and control sera and other biological samples, calibrating standards, and control charts.

(c) All equipment shall be in good working order, routinely checked and calibrated, and documentation of checks and calibrations shall be maintained.

(d) Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall be cleaned and sterilized prior to each use. Each sterilizing cycle shall contain an indicator device which assures proper sterilization.
(e) A specimen received by a laboratory shall not be tested or reported if:

1. The apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested.

2. It has been collected, labeled, preserved, or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.

3. It is perishable and the time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable.

4. When a specimen is not tested for any of the reasons specified in AAC Rule 420-5-8.04(4)(e), the laboratory shall promptly notify the sender and give the reason therefore.

(f) Notebooks or manuals containing appropriate current laboratory methods shall be maintained.

(5) Records and Reports.

(a) All changes in clinical laboratory personnel shall be reported to the Alabama Department of Public Health initially and annually at time of licensing.

(b) Modifications of facilities or services affecting the operation of the laboratory shall be reported to the Alabama Department of Public Health annually at the time of licensing.

(c) The laboratory shall participate in one or more of the proficiency testing programs offered by state or private organizations approved by the Alabama Department of Public Health. The results of such programs shall be made available to the Alabama Department of Public Health for review upon request.

(d) Records shall be maintained on each specimen received for testing and shall contain the following information:

1. Laboratory number or other identification of the specimen.

2. Name and other identification of the person from whom the specimen was taken.
3. Name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory that submitted the specimen.

4. Date the specimen was collected.

5. Condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, turbid).

6. Date the specimen was received.

7. Date the specimen was tested.

8. Type of test performed.

9. Complete information as to the disposition of the specimen when it has been referred to another laboratory for examination.

10. Result of test and date of reporting.

(e) The laboratory director is responsible for laboratory reports and the following records shall be maintained:

1. Tissue pathology reports utilizing acceptable terminology of a recognized system of disease nomenclature.

2. Duplicate copies of laboratory reports shall be filed in the laboratory or stored in a readily accessible location for at least two years.

3. Records and reports of examinations of all specimens shall be treated as confidential information.

(6) Collection Stations.

(a) Clinical laboratories operating collection stations within this state shall obtain a license from the Alabama Department of Public Health for each collection station. Such collection stations shall be maintained in accordance with the following requirements:

1. A refrigerator which maintains a temperature of 40-50 degrees F. shall be available on the premises for storage of specimens.
2. Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall be clean and sterile prior to use. Each sterilizing cycle shall contain an indicator device which assures proper sterilization.

3. Laboratory tests shall not be performed at collection stations.

4. Records shall be maintained indicating the daily accession of specimens containing the following information:
   (i) Name and other identification of the person from whom specimen was obtained.
   (ii) Name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory who submitted the specimen.
   (iii) Date the specimen was collected.
   (iv) Date the specimen was received.
   (v) Type of test requested.
   (vi) Name and address of referring laboratory or authorized person.

(b) Procedure manuals relating to the procedures performed by the collection station shall be maintained in laboratories and collection stations.

(7) **Plasmapheresis and Whole Blood Donor Centers.**

(a) Methods shall be provided for the selection of donors and for the collection, storage, processing and transfusion, which shall ensure as far as possible that: 1) the donation is not detrimental to the donor, and, 2) the recipient of the donated human blood or any of its components is protected from exposure to infectious diseases known to be transmissible by blood.

(b) Written policies and procedures shall conform to the current edition of the American Association of Blood Banks' Standards for Blood Banks and Transfusion Services. Copies of this reference may be purchased from: American Association of Blood Banks, 1117 North 19th Street, Suite 600, Arlington, Virginia 22209, telephone number 1-703-528-8200, or may be inspected at the office of the Alabama Department of Public Health, Division of Licensure and Certification, Laboratory Section, Montgomery, Alabama.
(c) Personnel Requirements.

1. Director shall meet at least the requirements specified in AAC Rule 420-5-8.03(1)(a)(1) and shall be responsible at all times for all phases of operation.

2. Donor Selection (Screening Area).

   (i) This area shall be staffed with at least one person with no lesser qualifications than that of a Licensed Practical Nurse (LPN), Clinical Laboratory Technician (MLT), or equivalent level of training or experience (approved by the Alabama Department of Public Health). Said qualified person shall be assigned the responsibility for supervision of all activities of the donor screening area (including such laboratory procedures as total serum protein, urine dipstick tests, hemoglobin and hematocrit testing).

   (ii) Every person employed in the screening area shall receive ongoing continuing or in-service education to enable him to recognize abnormalities that could make it detrimental to the donor to donate (i.e., problem with blood pressure, pulse, etc.) and to conduct careful evaluations of donor suitability in accordance with the outline for donor selection published by the American Association of Blood Banks. Documentation of the continuing or in-service education for each donor screening employee shall be available for review by the Alabama Department of Public Health.

3. Phlebotomy Area.

   (i) Phlebotomists shall be persons who have a minimum of one month's training in a plasmapheresis or blood donor center.

   (ii) A phlebotomist shall be employed for the care of each four (or fraction of four) donors being processed at one time.

   (iii) The phlebotomy area shall be supervised by a person with no lesser qualifications than that of a Licensed Practical Nurse (LPN), Clinical Laboratory Technician (MLT), or equivalent level of training and/or experience (approved by the Alabama Department of Public Health).
supervisor shall be certified in cardiopulmonary resuscitation (CPR) annually. It is permissible for one qualified person to supervise both the donor screening area and the phlebotomy area.

4. Plasmapheresis or Whole Blood Donor Testing Centers. Plasmapheresis or Whole Blood Donor Centers that perform any laboratory procedures other than screening procedures such as total serum protein, urine dipstick, hemoglobin and hematocrit testing, must comply with all provisions of the Alabama Administrative Code (AAC), Chapter 420-5-8, Rules of the Alabama State Board of Health for Independent Clinical Laboratories and Independent Physiological Laboratories.

5. Other Personnel. Aides, clerks, volunteer workers, etc., may be employed in the center but shall not perform technical duties.

(d) Proficiency Testing Requirements. The center shall participate in one or more of the proficiency testing programs approved by the Alabama Department of Public Health. The results of such programs shall be made available to the Alabama Department of Public Health for review.

(e) Quality Control Requirements. Quality control requirements shall be in accordance with AAC 420-5-8.04(4)(b).

(f) Documentation of Reactions.

1. The facility shall maintain a records system documenting all reactions.

2. Adequate reporting and recording forms shall be available and utilized.

Author: L. O’Neal Green, Rick Harris.

420-5-8.05 Specific Requirements for Independent Physiological Laboratories.

(1) Each independent physiological laboratory must have a governing body responsible for the management, control and operation of the facility. Said governing body is responsible for employing a qualified person to serve as the laboratory’s medical director. Any change in the appointment of the laboratory’s medical director must be promptly reported to the State Board of Health. Correspondence and inquiries from the
State Board of Health will be directed to the medical director, and the medical director is responsible for responding to same.

(2) Each independent physiological laboratory is required to maintain a permanent facility in Alabama where its records are kept. Any changes in the location of this facility must be submitted to this office for approval, prior to relocating.

(3) Each independent physiological laboratory shall employ or have under contract a physician who serves as the medical director of the laboratory. Said medical director must be a physician licensed to practice in Alabama. The medical director's duties are as follows:

(a) The medical director must provide written certification that each of the employees of the laboratory who perform diagnostic testing or services are appropriately trained and qualified to perform same. Such written certification, along with a current record showing each employee's training and qualifications is required to be maintained on site by the facility. The medical director is required to make a separate written certification for each employee on an annual basis. If an employee is not sufficiently trained or qualified to perform the duties assigned to that employee, then the medical director must not provide written certification for that employee and the laboratory must not permit the employee to perform such duties.

(b) Interpretation of the diagnostic physiological testing results must be performed by the medical director or other licensed physician. See paragraph (4) below for additional requirements for specific types of tests.

(c) The medical director is responsible for periodic verification that the equipment utilized by the laboratory is functioning properly and producing reliable and accurate results.

(d) The medical director is responsible for ensuring that the employees performing diagnostic physiological testing and services receive proper instruction or additional training when needed to maintain or acquire skills to adequately perform their duties, and is responsible for notifying the director of the laboratory when there are problems with personnel or equipment that require correction in order to maintain reliable and adequate testing results and services.

(4) Before performing carotid artery, abdominal aorta, ankle brachial vascular, or any other testing utilizing Doppler technology and ultrasonography on a patient, an independent physiological laboratory must comply with subsection (a) or (b).

(a) Receive a written order from a physician, licensed in Alabama, that specifies the name of the patient to be tested and the reason(s) the physician believes the patient should have the test(s). If the physician ordering the test(s) is the patient’s regular attending physician, the results shall be returned to that physician for appropriate follow-
up. If the physician ordering the test(s) is an employee or agent of the independent physiological laboratory, then the physician shall consult with the patient to explain the results and shall either conduct or arrange for follow-up tests, consultations, and/or procedures as medically necessary.

(b) For screening examinations to be performed in the absence of a written order from a physician, licensed in Alabama, that specifies the name of the patient to be screened and the reason(s) the physician believes the patient should have the screening examination, an independent physiological laboratory shall apply for and receive permanent written approval from the State Board of Health to conduct screening examinations. Any independent physiological laboratory approved under this subsection shall:

1. file annual reports with the Alabama State Department of Public Health containing the following information:

   (i) the number of patients screened in Alabama during that year;
   (ii) the number of patients screened during that year with results that indicated the need for follow-up care from a primary care physician;
   (iii) the number of patients screened during that year with results that indicated the need for immediate follow-up care from a primary care physician; and
   (iv) the number of patients in each above category who schedule a follow-up visit with a physician.

2. help any patient identify and contact a primary care physician, if such assistance is requested by the patient;

3. follow-up by telephone or letter with any patient whose results indicated the need for follow-up care from a primary care physician and advise the patient to contact a primary care physician; and

4. require that any screening examination performed is reviewed by a physician licensed in the state of Alabama and board certified in one or more of the following areas: cardiothoracic surgery, cardiology, vascular surgery, neurology, radiology, or in internal medicine with special training in vascular medicine.

(5) The laboratory must develop and follow a written procedure for adequate measures to prevent the spread of infection. Blood-letting or invasive devices capable of transmitting infection from one person to another shall be cleaned and sterilized prior to each use.

(6) Failure to permit inspection of the physiological laboratory and its records by representatives of the State Board of Health is a violation of these Rules.
(7) Any independent physiological laboratory which is a Medicare or Medicaid provider and licensed under these rules shall comply with applicable Medicare and Medicaid regulations.

Author: Rick Harris.

420-5-8.06 Building Requirements.

(1) Local Restrictions. The location and construction of all independent laboratories shall comply with local building and fire ordinances.

(2) Water Supply. If at all possible, all water shall be obtained from a public water supply. If it is impossible to connect to a public water system, the private water supply shall be approved by the County Health Department. Provisions shall be made for demineralized water. An adequate number of sinks and lavatories shall be provided to meet the needs of the laboratory. All water fixtures shall be equipped with vacuum breakers to preclude back-siphonage from any sink, lavatory, water closet, or other item of equipment.

(3) Disposal of Liquid and Human Wastes.

(a) There shall be installed within the building a properly designed waste disposal system, connecting to all fixtures to which water under pressure is supplied.

(b) All liquid and human waste, including floor wash water and liquid waste from refrigerators, shall be disposed through trapped drains into a public sewer system in localities where such systems are available.

(c) In localities where a public sanitary sewer is not available, liquid and human waste shall be disposed through trapped drains into a sewage disposal system approved by the local county health department and/or the State Board of Health. The sewage disposal system shall be of adequate size and capacity based on the number of personnel and patients using these facilities.

(4) Disposal of Flammable and Hazardous Materials. Disposal of all flammable and laboratory waste materials shall be in accordance with the requirements of the National Fire Protection Association's handbook number 56C. Instructions contained in this publication shall be extracted and developed into procedure
manuals that shall be available to all laboratory personnel. Procedures shall be established and enforced for the safe handling of all potentially infectious cultures and specimens and for the disposal of terminal disinfection of such materials, supplies, or equipment.

(5) **Housekeeping Facilities and Services.**

(a) Housekeeping facilities and services are required to be maintained to ensure comfortable and sanitary conditions.

(b) The physical plant shall be kept in a good state of repair, neat and attractive, and safety shall be the first consideration.

(6) **Temperature to be Maintained.** Temperature within the laboratory shall be maintained at a level consistent with comfortable working conditions and in keeping with special requirements for the performance of any particular procedure.

(7) **Communication.** A telephone and extensions shall be provided to ensure internal and external communication.

(8) **Exits.** The laboratory shall be provided with at least two exits remote from each other, leading directly to the outside or to an unobstructed passageway to the outside. Exits from the laboratory or any area used by patients shall be equipped with doors sufficient in width to accommodate wheelchairs. Exit doors shall open in the direction of exit travel.

(9) **Storage of Flammable Materials, Reagents, and Gases.** Storage of the items noted in this section shall be in accordance with the requirements of handbook number 56C of the National Fire Protection Association.

(10) **Fire Extinguishers and Personnel Safety Devices.**

(a) Fire extinguishers shall be provided in accordance with handbook number 56C of the National Fire Protection Association or as determined by the State Fire Control Authority.

(b) Emergency showers and eye baths or equivalent devices shall be provided in accordance with the requirements of handbook number 56C of the National Fire Protection Association.

(11) **Fire Plan.** A fire plan including fire evacuation routes shall be posted in conspicuous places. Fire drills shall be held at least semi-annually with all personnel participating and written reports of the effectiveness of these drills kept in writing.
(12) **Lighting.** Sufficient lighting shall be provided in all areas of the laboratory in keeping with the requirements for particular tests. Lighting of other areas shall be adequate to ensure safety for personnel and/or patients. Illuminated exit lights and direction signs shall be provided for each required exit.

**Author:** L. O’Neal Green, Rick Harris.

**Statutory Authority:** *Code of Alabama 1975*, 22-21-20, et seq.


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, assisted living facilities, and specialty care assisted living facilities rising to the level of intermediate care. 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. The term includes individuals, partnerships, corporations, and associations.

§ 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.

§ 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.

§ 22-21-23. License -- Application.

Any person desiring licensing under this article shall apply to the State Board of Health therefor. 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 and of reputable and responsible character. The applicant shall submit evidence of ability to comply with the minimum standards provided in this article or by regulations issued under its authority.

§ 22-21-24. License -- Fees; expiration and renewal; accreditation.

The application for a license to operate a hospital other than an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care shall be accompanied by a standard fee of two hundred dollars ($200), plus a fee of five dollars ($5) 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 two hundred dollars ($200) plus five dollars ($5) each for the net gain in beds. The initial licensure fee and subsequent annual licensure renewal fee for an assisted living facility and for a specialty care assisted living facility rising to the level of intermediate care shall be two hundred dollars ($200) plus fifteen dollars ($15) for each bed. A license renewal application for any hospital, as defined by this article, which is not received by the expiration date in a properly completed form and accompanied by the appropriate renewal fee shall be subject to a late penalty equal to two hundred fifty dollars ($250) or 100 percent of the renewal fee, whichever is greater. 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. A license granted under this article shall expire on December 31 of the year in which it was granted. A license certificate shall be on a form prescribed by the department, and shall be posted in a conspicuous place on the licensed premises. Licenses shall not be transferable or assignable and shall be granted only for the premises named in the application. Licenses 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.

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

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

(b) The State Board of Health may suspend or revoke a license granted 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 the institution.

(3) Conduct or practices deemed by the State Board of Health to be detrimental to the welfare of the patients of the institution.
(c) Before any license granted 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 the complaint, which date of hearing shall be not less than 30 days from the date of the notice. The 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.

§ 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.

§ 22-21-27. Advisory board.

(a) There shall be an advisory board of 17 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.

   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 Medical Association of the State of Alabama.

(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 who shall 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 Executive Committee of the Alabama Pharmacy Association.
(6) Three members who shall be appointed by the Executive Committee of the Alabama Nursing Home Association, each of whom shall be the operator of a duly qualified licensed nursing home.

(7) One member who shall be appointed by the Alabama Hospice Association.

(8) Two members who shall be appointed by the Assisted Living Association of Alabama, one of whom shall be the operator of a licensed assisted living facility or licensed specialty care assisted living facility rising to the level of intermediate care with 16 or fewer beds, and one of whom shall be the operator of an assisted living facility or licensed specialty care assisted living facility rising to the level of intermediate care with more than 16 beds.

(9) One member who shall be appointed by the Governor to represent the interests of consumers. The consumer representative shall be at least 65 years of age and shall have no financial interest in any facility licensed under this article.

Each new appointee shall serve for five years or until his or her successor is appointed, whichever is later. Any vacancy caused by a member leaving the position before the expiration of his or her term shall be filled by the organization selecting the original member. The replacement member appointed shall serve for the remainder of the unexpired term.

(c) A member of the advisory board shall not be eligible to succeed himself or herself after serving one full five-year term, but shall be eligible for reappointment if he or she has served only a portion of a five-year term or if he or she has not served immediately preceding the 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 the office at the same rate allowed state employees pursuant to general law.


(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 inimical 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. The procedure for adopting, amending, or rescinding any rules authorized by this article shall conform to the Alabama Administrative Procedure Act. At any public hearing called for the purpose of soliciting public comment on proposed rules, 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, pursuant to the Alabama Administrative Procedure Act. 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 as provided in the Alabama Administrative Procedure Act.

§ 22-21-29. Inspections.

(a) Every hospital licensed under this article shall be open to inspection to the extent authorized in this section by employees and agents of the State Board of Health, under rules as shall be promulgated by the board with the advice and consent of the advisory board. Employees and agents of the board shall also inspect unlicensed and suspected unlicensed facilities. 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 any 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 the 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.


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.

§ 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 Department of Human Resources or to any agency authorized or licensed by the Department of Human Resources to engage in child placing for such service as the child and the mother may require. In the rendering of service, representatives of the Department of Human Resources and agencies authorized or licensed by the Department of Human Resources shall have free access to visit the child and the mother concerned.


§ 22-21-33. Penalties for operation of or referring persons to unlicensed hospital.

(a) Any individual, association, corporation, partnership, limited liability company, or other business entity who operates or causes to be operated a hospital of any kind as defined in this article or any regulations promulgated hereunder, without having been granted a license therefor by the State Board of Health shall be guilty of a Class B misdemeanor upon conviction, except that any individual, association, corporation, partnership, limited liability company, or other business entity who operates or causes to be operated a hospital of any kind as defined in this article or any regulations promulgated hereunder without having been granted a license therefor by the State Board of Health shall be guilty of a Class A misdemeanor upon conviction of a second or any subsequent offense. The State Board of Health, upon determination that a facility or business is operating as a hospital, within the meaning of this article or any rules promulgated hereunder, and that the facility or business does not have a current and valid license granted by the State Board of Health, may apply to the circuit court of the county in which the unlicensed facility or business is located for declaratory and injunctive relief. The proceedings shall be expedited. The sole evidentiary questions before the court in a proceeding shall be whether the facility or business that is the subject of the action meets the definition of a hospital, within the meaning of this article and any rules promulgated hereunder, and whether the facility or business has been granted a current and valid license to operate by the State Board of Health. If the State Board of Health prevails on these questions, then the court shall, upon request of the State Board of Health, forthwith grant declaratory and injunctive relief requiring the operator or operators to close the facility or business and requiring the operator or operators to move all residents or patients to appropriate placements. Any individual failing to obey an injunction to close a hospital shall be guilty of a Class A misdemeanor. Any individual, after having once been subject to such an injunction, who shall later operate or cause to be operated a hospital, as defined in this article or any regulations promulgated hereunder, without having been granted a license therefor by the State Board of Health shall be guilty of a Class A misdemeanor. 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, or any individual, association, corporation, partnership, limited liability company, or other business entity, from operating, conducting, or managing a hospital in violation of any provisions of this article, or any regulation promulgated hereunder. Evidence that a person who is a licensed health care professional is or has been operating an unlicensed...
hospital or knowingly is or has been an employee of an unlicensed hospital shall be grounds for license revocation by the applicable professional licensing board or boards. No county or municipality shall grant a business license to a hospital, as defined in this article, unless the facility holds a current license to operate granted by the State Board of Health. In any action to collect a fee for services brought against a resident or patient by a hospital, as defined in this article or regulations promulgated hereunder, it shall be a defense to the action to demonstrate that the operator of the hospital did not have a current and valid license to operate pursuant to this article at the time the services in question were rendered.

(b) A licensed inpatient hospital acting through an authorized agent of the licensed inpatient hospital shall not knowingly refer to an unlicensed hospital any person who is in need of care rendered by a licensed hospital. A licensed hospice or certified home health agency acting through an authorized agent of the licensed hospice or certified home health agency shall not knowingly provide treatment or services in an unlicensed hospital to a person who is in need of care rendered by a licensed hospital. The Department of Public Health shall maintain, in electronic format and available on the Internet, a current directory of all licensed hospitals. The department shall publish and mail to licensed inpatient hospitals, licensed hospices, and certified home health agencies every three months a listing of licensed hospitals. A determination of actual knowledge that a facility or business was unlicensed shall be supported by evidence that the unlicensed hospital had not been listed in either the printed or electronic directory during the 12 months immediately prior to the time the referral was made or treatment provided. In any action to levy a fine or revoke a license under this section, it shall be a defense to the action to demonstrate that the unlicensed inpatient hospital appeared in the list published by the department, either electronically or in print format, as a licensed inpatient hospital during the 12 months immediately prior to the time the referral was made or the treatment was provided. Any licensed inpatient hospital acting through an authorized agent of the licensed inpatient hospital that knowingly makes a referral to an unlicensed hospital of a person in need of care rendered by a licensed hospital, or any licensed hospice or any certified home health agency acting through an authorized agent of the licensed hospice or certified home health agency that knowingly provides treatment in an unlicensed hospital to a person in need of care rendered by a licensed hospital, may be subject to a civil penalty imposed by the Board of Health not to exceed one thousand five hundred dollars ($1,500) per instance. All civil monetary penalties collected pursuant to this section or Section 22-21-34 shall be paid to the Department of Human Resources and held in a dedicated fund for the sole purpose of making grants or disbursements to assist protected persons, as this term is defined in Section 38-9-2 et seq, with appropriate placement or relocation from an unlicensed facility into a licensed facility or relocation from a facility undergoing license termination, suspension, or revocation, pursuant to Section 22-21-25, to an appropriate setting. The Department of Human Resources is hereby authorized to make grants or disbursements from this fund to protected persons or to individuals or public or private organizations acting on behalf of a protected person.

(c)(1) For the purposes of this section, the term “licensed inpatient hospital” shall mean a licensed acute care hospital, long-term acute care hospital, rehabilitation hospital, inpatient hospice, skilled nursing facility, intermediate care facility, assisted living facility, or specialized care assisted living facility.

(2) For the purposes of this section, the term “knowingly” shall mean actual knowledge by a licensed inpatient hospital, licensed hospice, or certified home health agency acting through an authorized agent making a referral or providing services, that the unlicensed hospital to which the referral is made or services rendered is unlicensed within the meaning of this section.
§ 22-21-34. Assisted living facility, etc., rising to level of intermediate care.

Under the circumstances listed below, an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care may be subject to a civil money penalty imposed by the Board of Health not to exceed ten thousand dollars ($10,000) per instance. The imposition of the penalty may be appealed pursuant to the Alabama Administrative Procedure Act. All money penalties imposed pursuant to this section shall be remitted to the Department of Public Health and shall be deposited in the State General Fund. The penalties shall be deposited in the General Fund and shall not be earmarked for the Department of Public Health. Failure of an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care to pay a civil money penalty within 30 days after its imposition or within 30 days after the final disposition of any appeal shall be grounds for license revocation unless arrangements for payment are made that are satisfactory to the State Board of Health. No assisted living facility or specialty care assisted living facility rising to the level of intermediate care may renew its license to operate if it has any unpaid civil money penalties which were imposed more than 30 days prior to the facility's license expiration date, except for any penalties imposed which are still subject to appeal and except for penalties for which arrangements for payment have been made that are satisfactory to the State Board of Health.

(1) A civil money penalty may be imposed for falsification of any record kept by an assisted living facility or specialty care assisted living facility rising to the level of intermediate care, including a medication administration record or any record or document submitted to the State Board of Health, by an employee or agent of the facility, where such falsification is deliberate and undertaken with intent to mislead the Board of Health, or its agents or employees, or residents, sponsors, family members, another state, county, or municipal government agency, or the public, about any matter of legal compliance, regulatory compliance, compliance with fire or life safety codes, or quality of care.

(2) A civil money penalty may be imposed as a result of a false statement made by an employee or agent of an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care to an employee or agent of the State Board of Health, if the statement is made with intent to deceive or mislead the Board of Health, its agents or employees, about any matter of legal compliance, regulatory compliance, compliance with fire or life safety codes, or quality of care. A civil money penalty shall not be imposed if the facility's employee or agent makes a false statement when he or she has no reason to believe the false statement is authorized by the administrator or operator of the facility and if it is likely that the facility's employee or agent made the statement with the intent to cause damage to the facility.