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 420-5-8
INDEPENDENT CLINICAL LABORATORIES

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 Ala. 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(f) "Collection Station" means a facility where materials or specimens are withdrawn or collected from patients for subsequent delivery to a clinical laboratory for examination.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 Ala. 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.

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