



PUBLIC NOTICE OF PROPOSED RULE CHANGES

Pursuant to the Georgia Administrative Procedures Act, Official Code of Georgia (O.C.G.A.) 50-13-1 et seq., the Georgia Department of Community Health is required to provide public notice of its intent to adopt, amend or repeal certain rules other than interpretive rules or general statements of policy. Accordingly, the Department hereby provides notice of its intent to amend the **Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10**. These changes are being proposed pursuant to the authority granted to the Department in O.C.G.A. §§ 31-2-5 and 31-2-7. An exact copy of the revised rules and a synopsis of the revisions are attached to this public notice.

NOTICE OF PUBLIC HEARING

An opportunity for public comment will be held on **August 15, 2017 at 10:00 a.m.**, at the Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303) in the 5th Floor Board Room. Oral comments may be limited to 10 minutes per person. Individuals who are disabled and need assistance to participate during this meeting should contact the Office of General Counsel at (404) 657-7195 at least three (3) business days prior to the meeting.

Citizens wishing to comment in writing on any of the proposed changes should do so on or before August 18, 2017. Comments may be faxed to (404) 656-0663, emailed to renee.robinson@dch.ga.gov or mailed to the following address:

Attention: Office of General Counsel
Georgia Department of Community Health
Post Office Box 1966
Atlanta, Georgia 30301

Comments from written and public testimony will be provided to the Board of Community Health prior to the September 2017 Board meeting. The Board will vote on the proposed changes at the Board meeting to be held at 10:30 a.m. on September 14, 2017 at the Georgia Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303 in the 5th Floor Board Room).

NOTICE IS HEREBY GIVEN THIS 13th DAY OF July, 2017.

Frank W. Berry, Commissioner

Attachments

**RULES
OF
GEORGIA DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION DIVISION
REVISE CHAPTER 111-8-10
RULES AND REGULATIONS FOR LICENSURE OF CLINICAL LABORATORIES**

SYNOPSIS OF PROPOSED RULE CHANGES

STATEMENT OF PURPOSE: The Georgia Department of Community Health proposes to revise the Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10. These changes are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. § 31-6-21 and O.C.G.A. § 31-6-21.1.

MAIN FEATURE OF THE PROPOSED RULE: Revision of the definition of "clinical laboratory" to comply with House Bill 210.

**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**CHAPTER 111-8
HEALTHCARE FACILITY REGULATION**

**111-8-10
LICENSURE OF CLINICAL LABORATORIES**

TABLE OF CONTENTS

111-8-10-.03 Definitions

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Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning here in after respectively ascribed to them:

- (a) **Analyte** means a substance or constituent for which the laboratory conducts testing;
- (b) **Board** means the Board of Community Health of the State of Georgia;
- (c) **Clinical Laboratory** means a facility for the biological, microbiological, serological, ~~immunological,~~ chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from ~~or produced by~~ the human body for the diagnosis of, recommendation of, treatment of, or for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings; the term "Clinical Laboratory" shall include specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its components ~~parts as well as~~ unless such human blood and its component parts are intended as source material for the manufacture of biological products and regulated by the Center for Biologics Evaluation and Research (CBER) within the federal Food and Drug Administration; the term "Clinical Laboratory" shall include tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings. The term 'clinical laboratory' shall not include laboratories which are nondiagnostic only and regulated pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) whose sole function is to perform examination of human blood or blood components intended as source material for the manufacture of biological products.
- (d) **CLIA-exempt state** means a state where the Centers for Medicare & Medicaid Services (CMS) has determined that the state has enacted laws/rules relating to laboratory requirements that are equal to or more stringent than CLIA requirements. All laboratories subject to state licensure will be considered as "CLIA exempt" where the state has been determined to be CLIA exempt;
- (e) **Commissioner** means the Commissioner of the Department of Community Health of the State of Georgia;
- (f) **Department** means the Georgia Department of Community Health;
- (g) **Director** means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results;

- (h) **Evaluation Program** means a state-conducted or state-approved proficiency testing program;
- (i) **Facility** means a building, structure, institution, place, or entity, which may be fixed or mobile;
- (j) **Laboratory Advisory Council** means the Clinical Laboratory, Blood Bank and Tissue Bank Committee authorized and required by law and appointed by the Board;
- (k) **Laboratory Test** means any examination and/or manipulation performed on a specimen produced by the human body, by procedures such as phlebotomy or blood diverted from a normal or life-sustaining circulatory path, or in vivo testing of body fluids for the purpose of diagnosis, treatment, monitoring or the assessment of the health of human beings;
- (l) **Limited specialty laboratory or limited laboratory specialty** means a clinical laboratory, or part of a clinical laboratory, in which testing is restricted (limited) to a designated category or subcategory, including but not necessarily limited to the following examples: cytology, histology, tissue banking, special chemistries (radio bioassay, blood gases, toxicology, etc.), cytogenetics and histocompatibility;
- (m) **Other Personnel** means non-technical personnel who may be employed in the laboratory such as aides, clerks, etc. These persons may assist laboratory technical staff, but do not themselves qualify as technical staff or perform tests;
- (n) **Person** means any individual, firm, partnership, association, corporation, the State or any municipality or other subdivision thereof, or any other entity whether organized for profit or not;
- (o) **Pertinent Laboratory Experience** means full time or equivalent work in a clinical laboratory, directing, supervising or performing tests in all categories, or, when limited to laboratory specialty(ies), work is restricted to that category/subcategory;
- (p) **Plan of Correction** means a written plan submitted by the laboratory director, owner, or other controlling authority, for approval by the Department. The plan shall identify the existing noncompliance of the laboratory and the proposed procedures, methods, means and reasonable period of time needed to correct the noncompliance;
- (q) **Point of Care Technician** means a medical professional person subject to these rules, who has received special training in point of care testing as defined by these rules. Medical professional staff authorized to perform point of care testing are limited to registered professional nurses, certified nurse practitioners, licensed practical nurses, certified respiratory care professionals, physician assistants, certified paramedics, certified emergency medical technicians, perfusionists, laboratory technologists, laboratory technicians and certified cardiovascular technologists, radiologic technologists certified by a professional credentialing

organization approved by the Department, and phlebotomists, certified by a professional credentialing organization approved by the Department;

- (r) **Point of Care Testing** means testing performed in the immediate proximity of the patient. All point of care testing must be approved by and under the supervision of a Georgia-licensed laboratory, unless the test site meets the requirements for exemption. All such point of care testing shall be approved only in the specialties for which the laboratory holds a license. Testing shall be limited to procedures which meet all current Georgia rules for quality control, quality assurance and Point of Care Testing personnel requirements. Point of Care Testing is exclusive of screening and monitoring tests;
- (s) **Quality Assurance** means a comprehensive process used by the laboratory to prevent and control errors that may occur at any interval from the time a test is ordered until it is reported and charted;
- (t) **Quality Control Program** means those quality control requirements established for clinical laboratories as provided in applicable federal law and regulations and in Georgia law and regulations;
- (u) **Screening and Monitoring Tests.** Screening tests mean those simple laboratory tests, approved by the Board as screening tests, used to aid in the detection of previously undiagnosed conditions. Monitoring tests mean those simple laboratory tests, approved by the Board as monitoring tests, with performance characteristics (accuracy and precision) that allow the tests to be used for evaluation of the status of previously diagnosed conditions and/or for evaluation of response to medical management;
- (v) **Specimen Collection Station** means a place or entity, without regard to location, that either collects specimens directly from patients or brings specimens together after collection for the purpose of forwarding them either intrastate or interstate to a licensed/certified clinical laboratory for examination;
- (w) **Specimen Collector and/or Phlebotomist** means any person who has been trained in procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis in Clinical Chemistry, Hematology, Immunohematology, Microbiology, and Immunology/Serology and who works under the general supervision of the laboratory director, supervisor or technologist;
- (x) **Supervisor** means an assistant to the director and a person with special scientific skills, who, under the general supervision of a clinical laboratory director, supervises technical personnel;
- (y) **Technician** means any person other than the clinical laboratory director, supervisor, technologist, or trainee who functions under the supervision of a clinical laboratory director, supervisor, or technologist and performs only those clinical laboratory procedures which require limited skill and responsibility and a

minimal exercise of independent judgment as described in 111-8-10-.06 (5)(a). The degree of supervision by the clinical laboratory director, supervisor, or technologist of a technician shall be determined by the director, supervisor, or technologist based on:

1. The complexity of the procedure to be performed;
2. The training and capability of the technician; and
3. The demonstrated competence of the technician in the procedure being performed;

- (z) **Technologist** means a person who performs clinical laboratory procedures which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training, experience, and certification.
- (aa) **Trainee** means a person who is enrolled in an accredited training program or who, in a limited laboratory specialty(ies) for which there is no accredited training program available, trains under the supervision of a director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory approval.