House Bill 93

By: Representative Cooper of the 43rd

A BILL TO BE ENTITLED

AN ACT

To amend Title 31 of the Official Code of Georgia Annotated, relating to health, so as to eliminate duplicative state licensure and regulation of clinical laboratories; to repeal provisions relating to examination of human specimens and methods for selection of blood donors and collection, storage, and processing of human blood; to eliminate state inspections of clinical laboratories; to amend Code Sections 26-4-172 and 42-1-10 of the Official Code of Georgia Annotated, relating to license requirements generally under the "Nuclear Pharmacy Act" and preliminary urine screen drug tests for inmates, respectively, so as to provide for conforming changes; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Title 31 of the Official Code of Georgia Annotated, relating to health, is amended by revising Chapter 22, relating to clinical laboratories, as follows:

″CHAPTER 22

31-22-1.

As used in this chapter, the term~~:~~

~~(1) 'Board' means the Board of Community Health.~~

(1) 'Certified' means certified by the federal Centers for Medicare and Medicaid Services pursuant to the federal Clinical Laboratory Improvement Amendments of 1988.

(2) 'Clinical laboratory' means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from 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 blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts 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~~.

~~(2.1) 'Commissioner' means the commissioner of community health.~~

~~(2.2) 'Department' means the Department of Community Health.~~

~~(3) '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.~~

~~(4) '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.~~

~~(5) 'Specimen collection station' means a place having the primary purpose of either collecting specimens directly from patients or bringing specimens together after collection for the purpose of forwarding them either intrastate or interstate to a clinical laboratory for examination.~~

~~(6) 'Supervisor' means an assistant director and a person who, under the general supervision of a clinical laboratory director, supervises technical personnel and performs tests requiring special scientific skills.~~

~~(7) '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. 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:~~

~~(A) The complexity of the procedure to be performed;~~

~~(B) The training and capability of the technician; and~~

~~(C) The demonstrated competence of the technician in the procedure being performed.~~

~~(8) 'Technologist' means a person who performs tests 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 he is qualified by education, training, and experience.~~

31-22-2.

~~(a)~~ No clinical laboratory shall be operated ~~without a license issued and in force pursuant to this chapter; provided, however, that the department may promulgate rules and regulations by which a facility or a part of a facility in which laboratory testing is done may qualify for exemption from licensure when only specific tests or techniques, designated by the department and used for screening and monitoring purposes only, are performed~~ in this state unless it is certified.

~~(b) Application for licenses shall be made to the Department of Community Health on forms prescribed by it. The application shall indicate the categories of procedures to be performed and shall contain such additional information as the department may require. Each application shall be accompanied by a nonrefundable fee prescribed by the department.~~

~~(c) The license applied for shall be issued if the department finds that all requirements are met or, in the case of a new clinical laboratory not yet in operation, that the owner is in a position to meet them. A license shall authorize the performance of one or more procedures or categories of procedures and shall be valid for one year from the date of issue unless sooner canceled, suspended, or revoked.~~

~~(d) A clinical laboratory license may be denied, revoked, suspended, limited, or renewal thereof denied on the following grounds:~~

~~(1) Making false statements of material information on an application for clinical laboratory license or any other documents required by the department;~~

~~(2) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;~~

~~(3) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations and procedures;~~

~~(4) Performing a test for or rendering a report to a person not authorized by law to receive such services;~~

~~(5) Referring a specimen for examination to a clinical laboratory in this state which has not been licensed pursuant to this chapter unless such referral laboratory is exempted from coverage of this chapter;~~

~~(6) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the name of the director and the name and address of the clinical laboratory in which the test was performed;~~

~~(7) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory;~~

~~(8) Violating or aiding in the violation of any provision of this chapter or the rules or regulations promulgated hereunder; or~~

~~(9) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.~~

~~(e) Each clinical laboratory shall have a licensed director. An individual shall be permitted to direct no more than three clinical laboratories. No individual shall function as a director of a clinical laboratory unless he is a physician licensed to practice medicine and surgery pursuant to Chapter 34 of Title 43; provided, however, that the director of a clinical laboratory restricting its practice to dental pathology may be either a physician licensed to practice medicine and surgery or a dentist licensed to practice dentistry; provided, further, that the board may promulgate rules and regulations which authorize persons who possess doctorate degrees in biology, microbiology, and related fields to be directors of clinical laboratories when the proper circumstances and qualifications are present.~~

~~(f) A clinical laboratory license shall specify on the face thereof the names of the owner and director, procedures or categories of procedures authorized, the location at which such procedures are to be performed, and the period for which the license is valid. The license shall be displayed at all times in a prominent place where it may be viewed by the public.~~

~~(g) Licenses issued pursuant to this chapter shall be subject to renewal in accordance with rules and regulations of the department.~~

~~(h) The board shall fix and publish in print or electronically and from time to time revise schedules of fees for applications and renewals. Such fees for clinical laboratory licenses shall be in amounts calculated to defray the costs of necessary inspections, evaluations, and investigations related thereto.~~

~~(i) The board shall promulgate rules and regulations which specify minimum standards for laboratory supervisors; provided, however, that nothing in this chapter shall be construed to affect any director, supervisor, technologist, or technician who is holding any such position on July 1, 1970.~~

~~(j) For the purposes of licensure, specimen collection stations which have a parent clinical laboratory licensed by the State of Georgia may be considered by the department to be part of that laboratory.~~

31-22-3.

Reserved.

31-22-4.

Reserved.

~~(a) A clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations.~~

~~(b) All specimens accepted by a clinical laboratory shall be tested on the premises or in another laboratory or location under the responsibility of the director unless forwarded to another properly licensed clinical laboratory.~~

~~(c) The results of a test shall be reported only to or as directed by the licensed physician, dentist, or other authorized person requesting such test. Such reports shall include the name of the director and the name and address of the clinical laboratory in which the test was performed.~~

~~(d) No person shall represent or maintain an office or specimen collection station or other facility for the representation of any clinical laboratory situated in this state or any other state which makes examinations in connection with the diagnosis and control of diseases unless the clinical laboratory so represented shall meet or exceed the minimum standards issued by the department pursuant to this chapter and the regulations issued under this chapter.~~

~~(e) The department may require laboratories to show evidence that specimens shipped through the mails and accepted by them for analysis are sufficiently stable for the determinations requested.~~

~~(f) Records involving clinical laboratory services and copies of reports of laboratory tests shall be kept for the period of time and in the manner prescribed by the department.~~

~~(g) Each clinical laboratory shall establish its own quality assurance program designed to ensure testing accuracy and in accordance with the rules and regulations promulgated by the department. The quality assurance program shall also include the use of, where applicable, calibration and control practices designed to ensure accurate and reliable test processes.~~

~~(h) Subsections (a) through (c) of this Code section shall not apply to the taking, examining, or testing of specimens by a clinical laboratory or its personnel solely in order to test the accuracy or sufficiency of its procedures or in order to make improvements in such procedures.~~

31-22-5.

Reserved.

~~(a) Those clinical laboratories which provide a system for the collection, processing, or storage of human blood and its component parts shall provide methods for the selection of blood donors as well as methods for the collection, storage, processing, and transfusion of blood, which shall ensure that the blood donation will not be detrimental to the donor and~~

~~to protect the ultimate recipient of human blood or any of its component parts from infectious disease known to be transmissible by blood.~~

~~(b) The methods described in subsection (a) of this Code section shall conform to the most recent 'Standards for Blood Banks and Transfusion Services' published by the American Association of Blood Banks; provided, however, that the board may modify the standards published by the American Association of Blood Banks by adopting separate or supplementary rules and regulations to ensure that the blood donation will not be detrimental to the donor and will protect the ultimate recipient of human blood or any of its component parts from diseases known to be transmissible by blood.~~

31-22-6.

In addition to powers conferred elsewhere in this chapter, the board shall~~:~~

~~(1) Promulgate~~ promulgate rules and regulations for the implementation of this chapter~~.~~;

~~(2) Establish and enforce standards governing the safety and sanitary requirements pertaining to clinical laboratories to the extent that they are not otherwise subject to requirements imposed by law or municipal ordinance; and~~

~~(3) Promulgate rules and regulations relating to the qualifications and performance of all personnel.~~

31-22-7.

~~(a)~~ The department shall require reporting by clinical laboratories of evidence of such infectious diseases as the department may specify and shall furnish forms for such reporting. No clinical laboratory making reports shall be held liable for having violated a trust or confidential relationship. The reports submitted shall be deemed confidential and not subject to public inspection.

~~(b) Every director of a clinical laboratory shall report to the department such information regarding the operation of the clinical laboratory as the department by its rules and regulations may require in order to aid in the proper administration of this chapter.~~

31-22-8.

Reserved.

~~(a) The department shall make periodic inspections of every clinical laboratory, at its discretion. In lieu of or to supplement its own inspection program, the department may use results of inspections conducted by other accrediting agencies. For the purpose of this subsection, the employees or agents of the department shall have the right of entry into the premises of the laboratory during normal hours of operation.~~

~~(b) The department shall operate a clinical laboratory evaluation program and shall prescribe standards of performance in the examination of specimens. As part of the clinical laboratory evaluation program, the department may require the clinical laboratory to analyze test samples submitted or authorized by the department and report on the results of such analysis.~~

31-22-9.

Reserved.

~~(a) This chapter shall not apply to clinical laboratories which are:~~

~~(1) Operated by the Georgia Health Sciences University, the Emory University School of Medicine, any other medical schools in Georgia, or the United States government;~~

~~(2) Operated and maintained exclusively for research and teaching purposes, involving no patient or public health services;~~

~~(3) Operated and maintained as part of a hospital regulated and licensed by the department at any period of time during which the department, as part of its licensure and regulation of such hospital, imposes upon the medical laboratory involved the same~~

~~standards of administration, performance, and operation as are imposed by this chapter upon medical laboratories covered in this chapter. In such cases and under such conditions, licensure of the hospital involved constitutes licensure of the hospital laboratory; or~~

~~(4) Operated by duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients.~~

~~(b) This chapter shall not apply to pharmacists licensed pursuant to Chapter 4 of Title 26, who shall be considered practicing within their scope of practice, when they are performing tests and interpreting the results as a means to screen for or monitor disease risk factors or drug use and facilitate patient education, so long as such tests are available to and for use by the public without licensure of the user of such tests. Pharmacists performing such tests shall make reasonable efforts to report the results obtained from such tests to the patient's physician of choice.~~

31-22-9.1.

(a) As used in this Code section, the term:

(1) 'AIDS' means Acquired Immunodeficiency Syndrome or AIDS Related Complex within the reporting criteria of the department.

(2) 'AIDS confidential information' means information which discloses that a person:

(A) Has been diagnosed as having AIDS;

(B) Has been or is being treated for AIDS;

(C) Has been determined to be infected with HIV;

(D) Has submitted to an HIV test;

(E) Has had a positive or negative result from an HIV test;

(F) Has sought and received counseling regarding AIDS; or

(G) Has been determined to be a person at risk of being infected with ~~AIDS,~~ HIV, and which permits the identification of that person.

(3) 'AIDS transmitting crime' means any of the following offenses specified in Title 16:

(A) Rape;

(B) Sodomy;

(C) Aggravated sodomy;

(D) Child molestation;

(E) Aggravated child molestation;

(F) Prostitution;

(G) Solicitation of sodomy;

(H) Incest;

(I) Statutory rape; or

(J) Any offense involving a violation of Article 2 of Chapter 13 of Title 16, regarding controlled substances, if that offense involves heroin, cocaine, derivatives of either, or any other controlled substance in Schedule I, II, III, IV, or V and that other substance is commonly intravenously injected, as determined by the regulations of the department.

(4) 'Body fluids' means blood, semen, or vaginal secretions.

(5) 'Confirmed positive HIV test' means the results of at least two separate types of HIV tests, both of which indicate the presence of HIV in the substance tested thereby.

(6) 'Counseling' means providing the person with information and explanations medically appropriate for that person which may include all or part of the following: accurate information regarding AIDS and HIV; an explanation of behaviors that reduce the risk of transmitting AIDS and HIV; an explanation of the confidentiality of information relating to AIDS diagnoses and HIV tests; an explanation of information regarding both social and medical implications of HIV tests; and disclosure of commonly recognized treatment or treatments for AIDS and HIV.

(7) 'Determined to be infected with HIV' means having a confirmed positive HIV test or having been clinically diagnosed as having AIDS.

(8) 'Health care facility' means any:

(A) Institution or medical facility, as defined in Code Section 31-7-1;

(B) Facility for mentally ill persons or persons with developmental disabilities, as such terms are defined in Code Section 37-1-1, or alcoholic or drug dependent persons, as defined in Code Section 37-7-1;

(C) Medical, dental, osteopathic, or podiatric clinic;

(D) Hospice, as defined in Code Section 31-7-172;

(E) Clinical laboratory, as defined in Code Section 31-22-1; or

(F) Administrative, clerical, or support personnel of any legal entity specified in subparagraphs (A) through (E) of this paragraph.

(9) 'Health care provider' means any of the following persons licensed or regulated by the state:

(A) Physician or physician assistant;

(B) Osteopath;

(C) Podiatrist;

(D) Midwife;

(E) Dentist, dental technician, or dental hygienist;

(F) Respiratory care professional, certified respiratory therapy technician, or registered respiratory therapist;

(G) Registered nurse;

(H) Licensed practical nurse;

(I) Emergency medical technician, paramedic, or cardiac technician;

(J) Clinical laboratory director, supervisor, technician, or technologist;

(K) Funeral director or embalmer;

(L) Member of a hospice team, as defined in Code Section 31-7-172;

(M) Nursing home administrator;

(N) Professional counselor, social worker, or marriage and family therapist;

(O) Psychologist;

(P) Administrative, clerical, or support personnel, whether or not they are licensed or regulated by the state, of any person specified in subparagraphs (A) through (O) of this paragraph;

(Q) Trainee, student, or intern, whether or not they are licensed or regulated by the state, of any persons listed in subparagraphs (A) through (O) of this paragraph; or

(R) First responder, as defined in Chapter 11 of this title, although such person is not licensed or regulated by the state.

(10) 'HIV' means any type of Human Immunodeficiency Virus, Human T-Cell Lymphotropic Virus Types III or IV, Lymphadenopathy Associated Virus Types I or II, AIDS Related Virus, or any other identified causative agent of AIDS.

(11) 'HIV infected person' means a person who has been determined to be infected with HIV, whether or not that person has AIDS, or who has been clinically diagnosed as having AIDS.

(12) 'HIV test' means any antibody, antigen, viral particle, viral culture, or other test to indicate the presence of HIV in the human body, which test has been ~~approved for such purposes by the regulations of the department~~ conducted by a certified clinical laboratory.

(13) 'Institutional care facility' means any:

(A) Health care facility;

(B) Child welfare agency, as defined in Code Section 49-5-12;

(C) Group-care facility, as defined in Code Section 49-5-3;

(D) Penal institution; or

(E) Military unit.

(14) 'Knowledge of being infected with HIV' means actual knowledge of:

(A) A confirmed positive HIV test; or

(B) A clinical diagnosis of AIDS.

(15) 'Law' means federal or state law.

(16) 'Legal entity' means a partnership, association, joint venture, trust, governmental entity, public or private corporation, health care facility, institutional care facility, or any other similar entity.

(17) 'Military unit' means the smallest organizational unit of the organized militia of the state, as defined in Code Section 38-2-2, or of any branch of the armed forces of the United States, which unit is commanded by a commissioned officer.

(18) 'Penal institution' means any jail, correctional institution, or similar facility for the detention of violators of state laws or local ordinances.

(19) 'Person' means a natural person.

(20) 'Person at risk of being infected with HIV' means any person who may have already come in contact with or who may in the future reasonably be expected to come in contact with the body fluids of an HIV infected person.

(21) 'Physician' means any person licensed to practice medicine under Chapter 34 of Title 43.

(22) 'Public safety agency' means that governmental unit which directly employs a public safety employee.

(23) 'Public safety employee' means an emergency medical technician, firefighter, law enforcement officer, or prison guard, as such terms are defined in Code Section 45-9-81, relating to indemnification of such personnel for death or disability.

(b) Notwithstanding the provisions of Code ~~Section 31-21-10 and Code Section~~ Sections 31-22-10 and 31-22-11, no person or legal entity, other than an insurer authorized to transact business in this state, shall submit for an HIV test any human body fluid or tissue to any person or legal entity except to:

(1) A clinical laboratory ~~licensed under this chapter~~ that is certified; or

~~(2) A clinical laboratory exempt from licensure under Code Section 31-22-9; or~~

~~(3)~~(2) A clinical laboratory licensed as such pursuant to the laws of any other state.

(c) No person or legal entity may sell or offer for sale any HIV test that permits any person or legal entity, including the person whose body fluids are to be tested, to perform that test other than a person or legal entity specified in paragraphs (1) ~~through (3)~~ and (2) of subsection (b) of this Code section.

31-22-9.2.

(a) Any term used in this Code section and defined in Code Section 31-22-9.1 shall have the meaning provided for that term in Code Section 31-22-9.1.

(b) Reserved.

(c) Unless exempted under this Code section, each health care provider who orders an HIV test for any person shall do so only after notifying the person to be tested. Unless exempted under this subsection, the person to be tested shall have the opportunity to refuse the test. The provisions of this subsection shall not be required if the person is required to submit to an HIV test pursuant to Code Section 15-11-603, 17-10-15, 31-17A-3, 42-5-52.1, or 42-9-42.1. The provisions of this subsection shall not be required if the person is a minor or incompetent and the parent or guardian thereof permits the test after compliance with this subsection. The provisions of this subsection shall not be required if the person is unconscious, temporarily incompetent, or comatose and the next of kin permits the test after compliance with this subsection. The provisions of this subsection shall not apply to emergency or life-threatening situations. The provisions of this subsection shall not apply if the physician ordering the test is of the opinion that the person to be tested is in such a medical or emotional state that disclosure of the test would be injurious to the person's health. The provisions of this subsection shall only be required prior to drawing the body fluids required for the HIV test and shall not be required for each test performed upon that fluid sample.

(d) The health care provider ordering an HIV test shall provide medically appropriate counseling to the person tested with regard to the test results. Such medically appropriate counseling shall only be required when the last confirmatory test has been completed.

(e) The criminal penalty provided in Code Section 31-22-13 shall not apply to a violation of subsection (c), (d), or (g) of this Code section. The statute of limitations for any action alleging a violation of this Code section shall be two years from the date of the alleged violation.

(f) The provisions of this Code section shall not apply to situations in which an HIV test is ordered or required in connection with insurance coverage, provided that the person to be tested or the appropriate representative of that person has agreed to have the test administered under such procedures as may be established by the Commissioner of Insurance after consultation with the Department of Community Health.

(g) Notwithstanding the other provisions of this Code section, when exposure of a health care provider to any body fluids of a patient occurs in such a manner as to create any risk that such provider might become an HIV infected person if the patient were an HIV infected person, according to current infectious disease guidelines of the Centers for Disease Control and Prevention or according to infectious disease standards of the health care facility where the exposure occurred, a health care provider otherwise authorized to order an HIV test shall be authorized to order any HIV test on such patient and obtain the results thereof:

(1) If the patient or the patient's representative, if the patient is a minor, otherwise incompetent, or unconscious, does not refuse the test after being notified that the test is to be ordered; or

(2) If the patient or the patient's representative refuses the test, following compliance with paragraph (1) of this subsection, when at least one other health care provider who is otherwise authorized to order an HIV test concurs in writing to the testing and the

patient is informed of the results of the test and is provided counseling with regard to those results.

31-22-10.

Nothing contained in this chapter shall be deemed or construed as affecting or repealing Chapter 23 of this title or Article 6 of Chapter 5 of Title 44.

31-22-11.

Nothing contained in this chapter shall be deemed or construed as affecting or repealing Chapter 34 of Title 43.

31-22-12.

The operation or maintenance of ~~an unlicensed~~ a clinical laboratory that is not certified, in violation of this chapter is declared a nuisance, inimical to the public health, welfare, and safety. The commissioner in the name of the people of the state through the Attorney General may, in addition to other remedies provided in this chapter, bring an action for an injunction to restrain such violation or to enjoin the future operation or maintenance of any such clinical laboratory until compliance with this chapter or the rules or regulations promulgated under this chapter has been demonstrated to the satisfaction of the department.

31-22-13.

Any person who violates any provision of this chapter or any of the rules and regulations promulgated pursuant thereto shall be guilty of a misdemeanor."

SECTION 2.

Code Section 26-4-172 of the Official Code of Georgia Annotated, relating to license requirements generally under the "Nuclear Pharmacy Act," is amended by revising subsection (c) as follows:

"(c) Nothing in this article shall be construed so as to require a ~~licensed~~ clinical laboratory certified by the federal Centers for Medicare and Medicaid Services, which is licensed by the Department of Community Health to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a nuclear pharmacy license, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals."

SECTION 3.

Code Section 42-1-10 of the Official Code of Georgia Annotated, relating to preliminary urine screen drug tests for inmates, is amended by revising subsection (b) as follows:

"(b) The Department of Corrections, Department of Community Supervision, and the State Board of Pardons and Paroles shall develop a procedure for the performance of preliminary urine screen drug tests in accordance with the manufacturer's standards for certification. Community supervision officers of the Department of Community Supervision or officials or employees of the Department of Corrections who are supervisors of any person covered under paragraphs (1) through (7) of subsection (a) of this Code section shall be authorized to perform preliminary urine screen drug tests in accordance with such procedure. Such procedure shall include instructions as to a confirmatory test by a ~~licensed~~ clinical laboratory certified by the federal Centers for Medicare and Medicaid Services where necessary."

SECTION 4.

All laws and parts of laws in conflict with this Act are repealed.