

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1313 Clinical Laboratory Personnel

SPONSOR(S): Chamberlin

TIED BILLS: **IDEN./SIM. BILLS:** SB 1108

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	14 Y, 0 N	Guzzo	McElroy
2) Health Care Appropriations Subcommittee	15 Y, 0 N	Aderibigbe	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Centers for Medicare and Medicaid Services (CMS), within the United States Department of Health and Human Services, regulates all laboratory testing performed on humans in the United States through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The Board of Clinical Laboratory Personnel (Board) within the Department of Health (DOH) oversees the licensure and regulation of clinical laboratory personnel, including directors, supervisors, technologists, technicians, and public health personnel. Licensure requirements for clinical laboratory personnel generally include passage of an exam designated by the Board, completion of a medical technology training program, and completion of applicable education requirements.

All applicants for licensure as a technologist must satisfy the CLIA training and education requirements for High Complexity Testing, and all applicants for licensure as a technician must satisfy the CLIA training and education requirements for Moderate Complexity Testing. In addition, Florida law requires an applicant for licensure as a technologist or technician to comply with additional education and training requirements for each specialty category of licensure.

The bill requires applicants for licensure to perform high or moderate complexity testing as a clinical laboratory technician or technologist to comply only with the federal CLIA education and training requirements. As a result, such applicants will not be required to also comply with the education and training requirements for specialty categories of technician and technologist licensure.

The bill repeals s. 483.811, which authorizes the Board of Clinical Laboratory Personnel to approve clinical laboratory personnel training programs. Training programs will be approved by accrediting organizations authorized under the CLIA. To conform with this change, the bill also removes authority for DOH to conduct exams, register trainers, and approve curriculum in schools and colleges, and removes authority for DOH to collect fees for exams and training programs.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Clinical Laboratory Personnel

A clinical laboratory is a facility in which human specimen is tested to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition.¹ Services performed in clinical labs include the examination of:²

- Fluids or other materials taken from the human body;
- Tissue taken from the human body; and
- Cells from individual tissues or fluid taken from the human body.

The Board of Clinical Laboratory Personnel (Board) within the Department of Health (DOH) oversees the licensure and regulation of clinical laboratory personnel, including directors, supervisors, technologists, and technicians.³ Licensure requirements for clinical laboratory personnel include completion of a medical technology training program,⁴ completion of applicable education requirements, and passage of an exam designated by the Board.⁵ The Board is authorized to collect fees for initial licensure, licensure renewal, examinations and reexaminations, and providers of laboratory training programs and for trainees of laboratory training programs.⁶

The Board is responsible for approving clinical laboratory training programs in hospitals or clinical laboratories.⁷ Any person who completes a training program must also pass an examination provided by DOH.⁸

The federal Centers for Medicare & Medicaid Services (CMS), within the United States Department of Health and Human Services, regulates all laboratory testing performed on humans in the United States through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).⁹ The CLIA define a clinical laboratory as any facility that examines materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. Any facility that meets this definition must have the appropriate CLIA certificate to perform laboratory tests. If a facility is only collecting specimens, a CLIA certificate is not required.

¹ S. 483.803(2), F.S.

² *Id.*

³ S. 483.805, F.S.

⁴ S. 483.111, F.S., and rule 64B3-3.001, F.A.C., authorize the Board to approve clinical laboratory training programs and requires approved training programs to: designate space and laboratory equipment for proper training of students; maintain a file on each student which contains a completed application, evidence of high school graduation or completion of college courses, attendance records, grades, instructor evaluations of laboratory practice, the trainee's registration, and a copy of the student's certificate of completion or official transcript; maintain current examinations and laboratory evaluation instruments utilized by the program; provide students with a certificate or letter of graduation or a transcript indicating the degree granted. Certificates or letters of graduation must be signed by the program director; include instruction in human immunodeficiency virus and acquired immunodeficiency syndrome; include instruction on the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety; include course objectives, course descriptions, course outlines, assessment of outcomes, student evaluations, and graduate evaluations in the curriculum; utilize educational resources for teaching the affective, cognitive, and psychomotor domains; employ systematic procedures for assessing learning outcomes in the affective, cognitive, and psychomotor domains; have a practicum in a clinical laboratory where current laboratory procedures, instrumentation, and diversity of specimens are available for a variety of analyses and are in sufficient quantity to provide competent training; and include instruction on Florida laws and rules governing clinical laboratories and clinical laboratory personnel.

⁵ S. 483.809, F.S.

⁶ S. 483.807, F.S.

⁷ S. 483.811(4), F.S.

⁸ *Id.*

⁹ 42 C.F.R. § 493.

Current Florida Law requires applicants for licensure as clinical laboratory personnel to comply with CLIA education and training standards.

Technologists

Clinical laboratory technologists may perform high complexity medical laboratory tests on patient samples including blood, urine, and tissue. Technologists may also interpret clinical laboratory test results.¹⁰ The specialist categories of technologist licensure include: generalist technologist (which includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology); blood banking specialist; cytology specialist; cytogenetics specialist; molecular pathology specialist; andrology and embryology specialists; histology specialist; and histocompatibility specialist.

All applicants for licensure as a technologist must satisfy the CLIA requirements for High Complexity Testing, which require the applicant to:¹¹

- Be a licensed doctor of medicine, osteopathy, or podiatric medicine; or
- Have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or
- Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution, or have education and training that is equivalent and includes:
 - At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses; and
 - Either completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools or the Committee on Allied Health Education and Accreditation (CAHEA). Or have at least three months of documented laboratory training in each specialty in which the individual performs high complexity testing.

In addition, Florida law requires an applicant for licensure as a technologist to comply with additional education and training requirements for each specialty category of technologist licensure.¹²

Generalist Technologist License

Licensure as a generalist technologist includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology. The education, training, and certification requirements for licensure as a generalist technologist include the following:¹³

- A bachelor's degree in clinical laboratory, chemical, or biological science; and
- A clinical laboratory training program approved by the National Accrediting Agency for Clinical Laboratory Science (NAACLS); and
- Certification as a medical laboratory scientist (MLS) or a medical technologist (MT); and
- Pass an examination (the National Registry of Certified Chemists or the national certifying body categorical examinations in a single discipline specialty area.

Or:

- A bachelor's degree in clinical laboratory, chemical, biological science, or a bachelor's degree with 24 semester hours of academic science including six semester hours of biological sciences and six semester hours of chemical sciences; and

¹⁰ Rule 64B3-10.005(2), F.A.C.

¹¹ Rule 64B3-5.003(2), F.A.C., and 42 C.F.R. § 493.1489.

¹² Rule 64B3-5.003(3), F.A.C.

¹³ Rule 64B3-5.003(3)(a), F.A.C.

- A clinical laboratory training program, or three years pertinent clinical laboratory experience with a minimum of six months in each specialty for which licensure is sought; and
- Certification as a MLS or a MT; and
- Pass an examination (the National Registry of Certified Chemists or the national certifying body categorical examinations in a single discipline specialty area.

Or:

- 90 semester hours of college credit with 24 semester hours of academic science, including six semester hours of biological sciences and six semester hours of chemical sciences; and
- A clinical laboratory training program; and
- Certification as a MLS or a MT; and
- Pass a MT examination or a specialist examination in a single discipline specialty area.

Or:

- An associate degree with six semester hours academic biological sciences and six semester hours of academic chemical sciences; and
- A clinical laboratory training program; and
- Certification as a MLS or a MT; and
- Pass a MT examination and a specialist examination in a single discipline specialty area.

Or:

- An associate degree with six semester hours of academic biological sciences and six semester hours of academic chemical sciences; and
- A clinical laboratory training program offered by the Department of Defense; or
 - Five years of pertinent clinical laboratory experience with one year of experience in each specialty area for which licensure is sought; and
- Pass a MT examination and a specialist examination in a single discipline specialty area.

Blood Banking Specialist

A blood banking specialist must:¹⁴

- Have a bachelor's degree in clinical laboratory, or chemical or biological science; and
- Have a clinical laboratory training program approved by the NAACLS; and
- Be certified in blood banking or as a MLS, MT, or a specialist in blood banking (SBB).

Or:

- Have a bachelor's degree in medical technology with 24 semester hours of academic science, six semester hours of biological science, and six semester hours of chemical science; and
- Be trained as required by the applicable certifying body; and
- Be certified in blood banking or as a MLS, MT, or a SBB.

Or:

- Have a bachelor's degree in clinical laboratory, or chemical or biological science, or a bachelors degree with 24 semester hours of academic science, six semester hours of biological science, and six semester hours of chemical science; and
- Have three years of pertinent clinical laboratory experience; or
 - A clinical laboratory training program; and
- Be certified in blood banking or as a MLS, MT, or a SBB.

Cytology Specialist

A cytology specialist must meet the education and training requirements of the American Society for Clinical Pathology (ASCP).¹⁵

Cytogenetics Specialist

A cytogenetics specialist must have a bachelor's degree with 30 hours of academic science and complete a board approved training program in cytogenetics at the technologist level or one year of pertinent clinical laboratory experience in cytogenetics. They must also be certified by the ASCP.¹⁶

Molecular Pathology Specialist

A molecular pathology specialist must:¹⁷

- Have a bachelor's degree with 16 semester hours of academic science; and
- Complete training as required by the applicable certifying body; and
- Be certified by the ASCP, the American Association of Bioanalysts, the American Board of Histocompatibility and Immunogenetics, or the American Medical Technologists.

Or:

- Meet education standards as required by the applicable certifying body; and
- Have one year of pertinent clinical laboratory experience in molecular pathology; and
- Be certified by the ASCP, the American Association of Bioanalysts (AAB), the American Board of Histocompatibility and Immunogenetics, or the American Medical Technologists.

Andrology and Embryology Specialists

Andrology and embryology specialists must:¹⁸

- Have a bachelor's degree with 24 semester hours of academic science, six semester hours of academic biological science, and six semester hours of academic chemical science; and
- Complete training as required by the AAB; and
- Be certified by the AAB; and
- Pass the AAB examination.

Or:

- Have an associate degree with six semester hours of academic biological science and six semester hours of academic chemical science; and
- Complete training as required by the AAB; and
- Be certified by the AAB; and
- Pass the AAB examination.

Histology Specialist

A histology specialist must:¹⁹

- Have an associate degree; and

¹⁵ Rule 64B3-5.003(3)(c), F.A.C.

¹⁶ Rule 64B3-5.003(3)(d), F.A.C.

¹⁷ Rule 64B3-5.003(3)(e), F.A.C.

¹⁸ Rule 64B3-5.003(3)(f), F.A.C.

¹⁹ Rule 64B3-5.003(3)(g), F.A.C.

- Complete a histotechnology training program approved by the NAACLS; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Complete training as required by the ASCP; and
- Be certified by the ASCP.

Or:

- Have 60 semester hours with 12 hours of chemical or biological science; and
- Complete a board approved training program; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Have three years of pertinent experience as a Florida licensed histology technician or equivalent; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Have five years of pertinent experience and 48 contact hours of continuing education in immunohistochemistry or advanced histologic techniques; and
- Be certified by the ASCP.

Or:

- Meet education standards as required by the ASCP; and
- Have five years of pertinent experience, 48 contact hours of continuing education in immunohistochemistry or advanced histologic techniques, and be a Florida licensed technician in the specialty of histology.

Histocompatibility Specialist

A histocompatibility specialist must be certified by the American Board of Histocompatibility and Immunogenetics (ABHI). To become certified, they must meet the education and training/experience standards of the ABHI.²⁰

Technicians

Clinical laboratory technicians are similar to technologists but they are not authorized to interpret clinical laboratory test results and may only perform moderate complexity tests, unless they meet the minimum qualifications for high complexity testing. Such a technician may perform high complexity testing only when under the direct supervision of a licensed technologist or the supervisor or director of the clinical laboratory.²¹

The specialist categories of technician licensure include: generalist technician (which includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and

²⁰ Rule 64B3-5.003(3)(h), F.A.C.

²¹ Rule 64B3-13.004, F.A.C.

immunohematology); histology specialist; andrology and embryology specialists; and molecular pathology specialist.

All applicants for licensure as a technician must satisfy the CLIA requirements for Moderate Complexity Testing, which require the applicant to:²²

- Be a licensed doctor of medicine, osteopathy, or podiatric medicine; or
- Have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;
- Have earned an associate degree in a chemical, physical, or biological science or medical laboratory technology from an accredited institution; or
- Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks, and have held the military enlisted occupational specialty of medical laboratory specialist; or
- Be a high school graduate or equivalent; and
 - Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.²³

In addition, Florida law requires an applicant for licensure as a technician to comply with additional education and training requirements for each specialty category of technician licensure.²⁴

Generalist Technician Licensure

Licensure as a generalist technician includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology. The education, training, and certification requirements for licensure as a generalist technician include the following:²⁵

- Have a bachelor's degree; and
- Have three years of pertinent clinical laboratory experience within the ten years immediately preceding application for licensure; and
- Be certified by the ASCP, the American Medical Technologists (AMT), or the AAB.

Or:

- Have an associate degree; and
- Have four years of pertinent clinical laboratory experience within the ten years immediately preceding application for licensure; and
- Be certified by the ASCP, the AMT, or the AAB.

Or:

- Meet education standards as required by the ASCP, the AMT or the AAB; and
- Complete an approved clinical/medical laboratory training program or have five years of pertinent clinical laboratory experience within the ten years immediately preceding application for licensure; and
- Be certified by the ASCP, the AMT, or the AAB.

²² Rule 64B3-5.004(2), F.A.C., and 42 C.F.R. § 493.1423.

²³ 42 C.F.R. § 493.1423. Such training must ensure that the individual has: the skills required for proper specimen collection, including patient preparation and labeling, handling, preservation, preparation, transportation, and storage of specimens; the skills required for implementing all standard laboratory procedures; the skills required for performing each test method and for proper instrument use; the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; the skills required to implement the quality control policies and procedures of the laboratory; the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results; a working knowledge of reagent stability and storage; and an awareness of the factors that influence test results.

²⁴ Rule 64B3-5.004(3), F.A.C.

²⁵ Rule 64B3-5.004(3)(a), F.A.C.

Histology Specialist

A histology specialist must be certified by the ASCP. To become certified, they must meet the education and training/experience standards of the ASCP.²⁶

Andrology and Embryology Specialists

Andrology and embryology specialists must:²⁷

- Have a bachelor's degree; and
- Have six months of pertinent clinical laboratory experience; and
- Be certified by the AAB.

Or:

- Have an associate degree; and
- Have five years of pertinent clinical laboratory experience; and
- Be certified by the AAB.

Or:

- Meet education standards as required by the AAB;
- Complete an approved clinical/medical laboratory training program; and
- Be certified by the AAB.

Molecular Pathology Specialist

Molecular pathology specialists must:²⁸

- Have a high school diploma; and
- Be a licensed clinical laboratory technologist or technician in any specialty area; and
- Pass the molecular diagnostics examination; and
- Be certified by the AAB.

²⁶ Rule 64B3-5.004(3)(b), F.A.C.

²⁷ Rule 64B3-5.004(3)(c), F.A.C.

²⁸ Rule 64B3-5.004(3)(d), F.A.C.

Effect of the Bill

The bill requires applicants for licensure to perform high or moderate complexity testing as a clinical laboratory technician or technologist to comply only with the federal CLIA education and training requirements. As a result, such applicants will not be required to also comply with the education and training requirements for specialty categories of technician and technologist licensure.

The bill repeals s. 483.811, which authorizes the Board of Clinical Laboratory Personnel to approve clinical laboratory personnel training programs. Training programs will be approved by accrediting organizations authorized under the CLIA. To conform with this change, the bill also removes authority for DOH to conduct exams, register trainers, and approve curriculum in schools and colleges, and removes authority for DOH to collect fees for exams and training programs

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 483.809, F.S., relating to licensure; examinations; registration of trainees; approval of curricula.

Section 2: Repeals s. 483.811, F.S., relating to approval of laboratory personnel training programs.

Section 3: Amends s. 483.823, F.S., relating to qualifications of clinical laboratory personnel.

Section 4: Amends s. 483.800, F.S., relating to declaration of policy and statement of purpose.

Section 5: Amends s. 483.803, F.S., relating to definitions.

Section 6: Amends s. 483.807, F.S., relating to fees; establishment; disposition.

Section 7: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See fiscal comments.

2. Expenditures:

See fiscal comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill has no fiscal impact on DOH. The reduction in revenue from the non-collection of fees for exams and training programs will be offset by a reduction in workload for DOH because they will no longer be required to conduct exams, register trainers, or approve curricula.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not necessitate rule-making.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES