The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1374
INTRODUCER:	Senator Rodriguez
SUBJECT:	Clinical Laboratory Testing
DATE:	February 1, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Pre-meeting**
2.			AP	
3.			RC	

I. Summary:

SB 1374 amends s. 483.801, F.S., to exempt persons performing alternate-site clinical laboratory testing within a hospital or hospital-based off-campus emergency department licensed under ch. 395, F.S., from the application of the requirements of Part I of ch. 483, F.S.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

The Department of Health

The Legislature created the DOH to protect and promote the health of all residents and visitors in the state.[1] The DOH is charged with the regulation of health practitioners for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA) is responsible for the boards[2] and professions within the DOH.[3]

Clinical Laboratories

Part I of ch. 483, F.S., regulates clinical laboratories and laboratory personnel. The purpose of this part is to protect the public health, safety, and welfare of the people of Florida from the hazards of improper performance by clinical laboratory personnel.

[1] Section 20.43, F.S.
[2] Section 456.001(1), F.S., defines "board" as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the MQA.
[3] Section 20.43, F.S.

In s. 483.800, F.S., the Legislature declares that clinical laboratories provide essential services to practitioners of the healing arts[4] by furnishing vital information that is essential to a determination of the nature, cause, and extent of the condition involved. Unreliable and inaccurate reports may cause unnecessary anxiety, suffering, and financial burdens and may even contribute directly to death. The protection of public and individual health requires the licensure of clinical laboratory personnel who meet minimum requirements for safe practice. The Legislature finds that laboratory testing technology continues to advance rapidly.[5]

A clinical laboratory is the physical location in which services are performed 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.[6] Services performed in clinical labs include:[7]

- The examination of fluids or other materials taken from the human body;
- The examination of tissue taken from the human body; and
- The examination of cells from individual tissues or fluid taken from the human body.

Federal Clinical Laboratory Regulations

Clinical laboratories that provide testing services in Florida must be certified by the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) program.[8] The CLIA program sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens and applies to all laboratories seeking payment under the Medicare and Medicaid programs.[9] The CLIA program categorizes laboratory tests by complexity (waived tests, tests of moderate complexity, and tests of high complexity) and must be either CLIA-exempt or possess a CLIA program certificate for each category of tests the clinical laboratory will perform.[10]

Under the CLIA program, a clinical laboratory performing waived tests, tests of moderate complexity, or test of high complexity, or any combination of the three, must file a separate applications for each laboratory location, unless it fits one of the following exceptions:

- Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may be covered under the certificate of the designated primary site or home base, using its address;
- Not-for-profit or federal, state, or local government laboratories that engage in limited public health testing[11] may file a single application; and

[4] Section 483.803(7), F.S., defines "licensed practitioners of the healing arts" as licensed allopathic physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, naturopaths, and dentists.
[5] Section 483.800, F.S.
[6] Section 483.803(2), F.S.
[7] Section 483.803(a) - (c), F.S.
[8] Section 395.009(1), F.S.
[9] 42 C.F.R. s. 493.1.
[10] 42 C.F.R. s. 493.5.
[11] "Limited" means not more than a combination of 15 moderately complex or waived tests per certificate.

- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.[12]

A CLIA program certified clinical laboratory must also meet the federal requirements related to laboratory testing personnel in 42 C.F.R. ss. 493.1406 through 493.1491.

The CLIA program requires that each individual performing high complexity testing must possess a state-issued license if licensure is required in the state in which the laboratory is located, and meet one of the following requirements:[13]

- Be a licensed allopathic or osteopathic physician (MD or DO), or doctor of podiatric medicine (DPM); or
- Have earned a doctorate, master's, or bachelor's in laboratory science; or
- Have earned an associate degree in laboratory science with the following; or
  - 60 semester hours including 24 semester hours of medical lab technology; or,
  - 60 semester hours including 24 hours of science that includes six hours of chemistry, six hours of biology, and 12 hours of chemistry, biology or, medical lab technology in any combination and laboratory training that includes either:
    - Completion of a clinical lab training program; or
    - Three months of training in each specialty the high complexity testing is performed; or
- Previously qualified or could have qualified as a technologist under federal regulations prior to February 28, 1992.

The CLIA program requires that each individual performing moderate complexity testing must possess a state-issued license if licensure is required in the state in which the laboratory is located, and meet one of the following requirements:[14]

- Be qualified to perform high complexity testing; or
- Be a licensed MD, DO, or DPM; or
- Have earned a doctorate, master's, bachelor's, or associate's degree in laboratory science; or
- Be a high school graduate or equivalent, and
  - Have had 50 weeks military training as medical lab specialist; or
  - Have documentation of training appropriate to testing to be performed. Training must ensure skills in:
    - Specimen collection, labeling, preparation, etc.;
    - Implementing laboratory procedures;
    - Performing assigned tests;
    - Conducting preventative maintenance, troubleshooting, calibration;
    - Knowledge of reagent stability and storage;
    - Implementing quality control (QC) procedures;
    - Knowledge of factors influencing test results; and
    - Validating patient test results with QC before reporting.

[12] 42 C.F.R. ss. 493.35, 493.43 and 493.55.
[13] 42 C.F.R. s. 493.1489.
[14] 42 C.F.R. s. 493.1423.

There are no specific CLIA program requirements for clinical laboratory personnel performing waived testing only.

Clinical Lab Personnel

In addition to the federal CLIA program clinical laboratory personnel requirements set out in 42 C.F.R. 493.1406 through 493.1491, clinical laboratories in Florida must also meet the clinical laboratory personnel requirements in part I, ch. 483, F.S.

"Clinical laboratory personnel" in Florida includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities.[15]

The Board of Clinical Laboratory Personnel (Board) oversees the licensure and regulation of clinical laboratory personnel, including supervisors, technologists, technicians, directors, and public health laboratory personnel. Generally, licensure requirements for clinical laboratory personnel include passage of an exam designated by the Board, completion of a medical technology training program, and completion of applicable education requirements.[16]

Part I of ch. 483, F.S., applies to all clinical laboratories and clinical laboratory personnel within this state, except:[17]

- Clinical laboratories operated by the U.S. government;
- Laboratories operated exclusively for research and teaching purposes, involving no patient or public health services;
- Persons engaged in testing in laboratories that are wholly owned and operated by one or more licensed allopathic physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, naturopaths, optometrists or dentists who practice in the same group practice, and perform no testing on patients for non-member group member healthcare providers;
- Respiratory therapists and respiratory care practitioners certified or registered under Part V of ch. 468. F.S.;
- Advanced practice registered nurses licensed under Part I of ch. 464, F.S., who are engaged in performing provider-performed microscopy procedures in laboratories that are wholly owned and operated by one or more licensed allopathic physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, naturopaths, optometrists and dentists who practice in the same group practice; and
- Persons performing laboratory testing within a physician's office for patients referred by a health care provider who is a member of the same physician office practice, if the laboratory or entity operating the laboratory within a physician office practice is under common ownership, directly or indirectly, with an entity licensed under ch. 395, F.S.

[15] Section 483.803(4), F.S.
[16] Section 483.809, F.S. and Fla. Admin. Code R. 64B3-5, (2021).
[17] Section 483.801, F.S.

Alternate-site Lab Testing

The term "alternate-site testing" includes any laboratory testing done under the administrative control of a hospital but performed out of the physical or administrative confines of the central laboratory.[18] Alternate-site testing locations are hospital units or departments on the hospital premises that are located outside of the physical or administrative confines of the hospital's central laboratory, but are still under the administrative control of the hospital and under the supervision of the laboratory director.[19]

A hospital laboratory may operate more than one alternate-site. A Florida hospital is required to provide on the premises, or by contract, clinical and pathology laboratory services commensurate with the hospital's needs. The hospital laboratory, and any contracted laboratory providing services for hospital patients, must be certified by the federal Centers for Medicare & Medicaid Services (CMS) under the federal CLIA program and the federal rules adopted thereunder in all specialties or subspecialties in which testing is performed. Hospitals may operate more than one CLIA program certified laboratory on site or at satellite locations that are certified by the CLIA program and on the same or adjoining grounds of a hospital licensed under ch. 395, F.S.[20]

Section 395.0091, F.S., requires the Agency for Health Care Administration (AHCA), in consultation with the Board, to adopt by rule criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director.[21]At a minimum, the criteria must include the following:

- The hospital's internal needs assessment;
- A protocol for implementation, including the identification of tests to be performed and who will perform them;
- Selection of the method of testing to be used for alternate-site testing;
- Minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals;
- Documented in-service training and initial and ongoing competency validation;
- An appropriate internal and external quality control protocol;
- An internal mechanism for the central laboratory to identify and track alternate-site testing; and
- Recordkeeping requirements.

Alternate-site testing locations must be registered when the hospital applies to renew its license.[22]

Current AHCA rule does not require authorized alternate-site testing personnel to be licensed under Part I of ch. 483, F.S., as laboratory personnel but does require personnel to have a high

[18] Section 395.0091, F.S.
[19] Fla. Admin. Code R. 59A-3.242 (1)(g), (2021).
[20] Section 395.002(13)(b), F.S. and Fla. Admin. Code R. 59A-3.242 (1), (2021).
[21] Fla. Admin. Code R. 59A-3.242 (1), (2021).
[22] Section 395.0091, F.S.

school diploma or its equivalent, satisfy the HIV/AIDS educational requirements of s. 381.0035, F.S., and be licensed or certified as one of the following:[23]

- Emergency medical technician;
- Paramedic;
- Physician assistant;
- Anesthesiologist assistant;
- Advanced practice registered nurse;
- Registered nurse;
- Licensed practical nurse;
- Radiologic technologist;
- Respiratory care practitioner in critical care services;
- Respiratory therapist;
- Clinical laboratory director, supervisor, technologist, technician, or person exempt from such licensure;
- Phlebotomist;
- Clinical laboratory assistant;
- Medical laboratory assistant;
- Perfusionist with specific experience; or
- Cardiovascular technician.

The laboratory director will determine if the personnel listed above are suitable to perform testing at an alternate-site.[24]

Hospital-Based Off-Campus Emergency Departments

Section 395.002(10), F.S., defines a hospital-based off-campus emergency department (HB-OCED) to mean a facility that:

- Provides emergency services and care;
- Is owned and operated by a licensed hospital and operates under the license of the hospital; and
- Is located on separate premises from the hospital.

Florida Administrative Code Rule 59A-3.066(2)(e), relating to hospital licensure procedures, also refers to, "off-site emergency departments" in regard to hospital licensure applications for additional off-site emergency departments. The American College of Emergency Physicians defines a hospital-based, freestanding emergency department (HB-FED) as a licensed facility that is structurally separate and distinct from a hospital and provides emergency care, and is also referred to as an off-site, hospital-based or satellite emergency department.[25] CMS refers to these

[23] Fla. Admin. Code R. 59A-3.242(1)(g)(6)d., (2021).
[24] Fla. Admin. Code R. 59A-3.242(1)(g)(6)e., (2021).
[25] American College of Emergency Physicians, Policy Statement, *Freestanding Emergency Departments*, June, 2014, Rev. Apr., 2020, available at https://www.acep.org/patient-care/policy-statements/freestanding-emergency-departments/ (last visited Jan. 26, 2022).

facilities as Provider-based Off-campus Emergency Departments and requires them to operate under the license of the main provider for purposes of Medicare reimbursement.[26]

In Florida, any licensed hospital which has a dedicated emergency department may provide emergency services in a location separate from the hospital's main premises.[27] A single license will be issued to a licensee for facilities located on separate premises, upon request of the applicant. The license will specifically state the location of the facility, its services, and the licensed beds available on each separate premises.[28] Additional statutory requirements for HB-OCEDs may be found in s. 395.1041(3)(m), F.S., but none relate to clinical laboratory services.

The AHCA interprets existing law to allow a licensed hospital to establish and operate a HB-OCED as part of the facility operations, similar to other hospital outpatient departments, without a separate license. A hospital that wishes to establish a HD-OCED is required to get approval from the AHCA's Office of Plans and Construction.[29]

Under current federal CLIA program regulations, a HB-OCED would be unable to operate an onsite clinical laboratory or perform clinical laboratory tests, though the use of the mobile laboratory testing service exemption would allow it to make clinical laboratory services available to patients.

III. Effect of Proposed Changes:

SB 1374 amends s. 483.801, F.S., to exempt persons performing alternate-site clinical laboratory testing within a hospital or HB-OCED licensed under ch. 395, F.S., from the application of the requirements of Part I of ch. 483, F.S.

The bill provides an effective date of July 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

[26] 42 C.F.R. ss. 413.65(a)(2) and (d)(1) (2017). *See also* U.S. Department of Health & Human Services, Centers for Medicaid & Medicare Services, *Requirements for Provider-based Off-campus Emergency Departments* (Jan. 11, 2008), available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter08-08.pdf (last visited Jan. 26, 2022).

[27] Section 395.002(23), F.S., defines "premises" as those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital or ambulatory surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07, F.S., reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within one mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

[28] Fla. Admin. Code R. 59A-3.066(2)(i), (2021).

[29] Fla. Admin. Code R. 59A-3.066(2)(e), (2021). *See also* Fla. Admin. Code R. 59A-3.080, (2021).

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill might conflict with the federal CLIA program requirements in 42 C.F.R., part 493. The federal CLIA program clinical laboratory location and personnel regulations still apply, even with a state exemption.

VIII. Statutes Affected:

This bill substantially amends section 483.801 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.