HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 931 Alternate-site Testing
SPONSOR(S): Professions & Public Health Subcommittee, McClure
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 1374

FINAL HOUSE FLOOR ACTION: 117 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 931 passed the House on March 8, 2022, as CS/CS/SB 1374.

A clinical laboratory is the facility in which human specimens are 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. Hospitals and clinical laboratories are regulated by the Agency for Health Care Administration (AHCA) and federal law. The Board of Clinical Laboratory Personnel (Board) within the Department of Health (DOH) licenses and regulates clinical laboratory personnel, including supervisors, technologists, technicians, directors, and public health laboratory personnel. With limited exceptions, including certain laboratories and health care practitioners, only licensed clinical laboratory personnel may perform clinical laboratory testing.

A hospital central laboratory, and federally certified satellite laboratories,may perform clinical laboratory testing. Current law allows alternate-site testing, which is any laboratory testing done under the administrative control of a hospital and the supervision of the laboratory director, but performed out of the physical or administrative confines of the hospital's central laboratory. This allows tests to be performed bedside, at a nurse station, in an operating or emergency room, or anywhere else under the administrative control of a hospital. Current AHCA rule authorizes advanced practice registered nurses, registered nurses, licensed practical nurses, and licensed clinical laboratory personnel to perform testing at alternate sites.

A freestanding emergency department (FED) is a hospital-based facility that receives individuals for emergency care and is physically separate from a hospital. Only licensed clinical laboratory personnel may perform clinical laboratory testing in a FED.

The bill exempts licensed registered nurses from clinical laboratory personnel licensure requirements. This allows registered nurses to perform certain alternate-site testing within a hospital or a FED that is separately certified by the federal Clinical Laboratory Improvement Amendment. The bill requires the laboratory director of the hospital or FED to determine if the registered nurse is qualified to perform such testing.

The bill has no fiscal impact on AHCA, DOH, or local governments.

The bill was approved by the Governor on April 6, 2022, ch. 2022-37, L.O.F., and will become effective on July 1, 2022.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Clinical Laboratories

A clinical laboratory is the physical location 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:[2]

- 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.

Clinical laboratories that provide testing services in this state must be certified by the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) program.[3] The CLIA program issues five types of certificates:[4]

- **Certificate of Waiver:** Issued to a laboratory that performs only waived tests;
- **Certificate of Provider-Performed Microscopy Procedures:**[5] Issued to a laboratory in which a physician, midlevel practitioner, or dentist performs specific microscopy procedures during the course of a patient's visit. This certificate permits the laboratory to also perform waived tests;
- **Certificate of Registration:** Issued to a laboratory to allow the laboratory to conduct nonwaived testing until the laboratory is inspected to determine its compliance with CLIA regulations;
- **Certificate of Compliance:** Issued to a laboratory after a survey is conducted and the laboratory is found to be in compliance with all applicable CLIA requirements; and
- **Certificate of Accreditation:** Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by the CMS.

CLIA categorizes laboratory tests by complexity: waived tests;[6] tests of moderate complexity; and tests of high complexity.[7] The standards for moderate and high complexity testing differ only in the personnel requirements. Laboratories must be either CLIA-exempt or possess a CLIA program certificate for each category of tests the clinical laboratory will perform.[8]

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[1] Section 483.803, F.S.
[2] Ss. 483.803(2)(a)-(c), F.S.
[3] Section 395.009(1), F.S.
[4] Centers for Medicare and Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA): How to Obtain a CLIA Certificate*, (March 2006), https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf (last visited March 8, 2022). All certificates are effective for two years.
[5] Center for Surveillance, Epidemiology, and Laboratory Services, *Provider-Performed Microscopy Procedures: A Focus on Quality Practices*, February 2016, https://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020-A_Stang_PPMP_Booklet_FINAL.pdf (last visited March 8, 2022). PPMPs are a select group of moderately complex microscopy tests commonly performed by health care providers during patient office visits. Tests included in PPMP do not meet the criteria for waiver because they are not simple procedures, but rather require training and specific skills to conduct such tests.
[6] Waived tests are simple laboratory examinations and procedures that have an insignificant risk of erroneous result; any other tests are considered non-waived. Examples of waived tests include urine dipstick, blood glucose, etc. A full list of waived tests can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm (last visited March 8, 2022).
[7] 42 C.F.R. s. 493.5. Tests of moderate and high complexity are not simple procedures, but rather require training and specific skills to conduct such tests. See U.S. Centers for Disease Control and Prevention, *Test Complexities,* https://www.cdc.gov/clia/test-complexities.html (Last vistited March 8, 2022).
[8] Id.

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 application for each laboratory location, unless it fits one of the following exceptions:[9]

- 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[10] public health testing may file a single application; and
- 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.

Clinical Laboratory Personnel

The Board of Clinical Laboratory Personnel (Board) within the Department of Health (DOH) 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.[11]

Current law provides exemptions from the application of part I of ch. 483, F.S., which regulates clinical laboratory personnel. Exemptions include:[12]

- Clinical laboratories operated by the United States Government;
- Laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health service whatsoever;
- Persons engaged in testing performed by 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 in which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that group practice;
- Respiratory therapists and respiratory care practitioners certified or registered under part V of chapter 468;
- Advanced practice registered nurses licensed under part I of chapter 464 who perform provider-performed microscopy procedures in a laboratory setting; and
- Persons performing laboratory testing within a physician office practice 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 pursuant to chapter 395.

Registered Nurses

The Board of Nursing (BON) within DOH, oversees the licensure and regulation of certified nursing assistants, licensed practical nurses, registered nurses, and advanced registered nurse practitioners. The BON has the authority to adopt rules to implement ch. 464, F.S., which regulates the practice of nursing in this state.[13]

[9] 42 C.F.R. ss. 493.35, 493.43 and 493.55.
[10] "Limited" means not more than a combination of 15 moderately complex or waived tests per certificate.
[11] Section 483.809, F.S. and ch. 64B3-5, F.A.C.
[12] Section 483.801, F.S.
[13] Section 464.006, F.S.

A registered nurse is licensed to practice "professional nursing," which is the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skill based upon applied principles of psychological, biological, physical, and social sciences.[14] To be licensed as a registered nurse, among other things, an individual must complete an associate's degree consisting of 50 percent clinical training or a bachelor's degree consisting of 40 percent clinical training from a BON-approved education program.[15]

Currently, registered nurses licensed under ch. 464, F.S., may perform testing for patients in a hospital under their current license, but must possess a clinical laboratory personnel license when performing testing outside of a hospital setting.

Alternate-Site Laboratory Testing

Hospitals are goverened under ch. 395, F.S., and regulated by the Agency for Health Care Administration (AHCA).

Generally, a hospital's main or central laboratory or satellite laboratories that are certified by CLIA established on the same or adjoining grounds of a hospital licensed under ch. 395, F.S., may perform clinical laboratory testing.[16] Testing at satellite labs must be done by licensed clinical laboratory personnel. Section 395.0091, F.S., allows for alternate-site testing, which is any laboratory testing done under the administrative control of a hospital and the supervision of the laboratory director, but performed outside of the physical or administrative confines of the hospital's central laboratory. This allows tests to be performed bedside, at a nurse station, in an operating room or the emergency room, or anywhere else under the administrative control of a hospital.

Current AHCA rule authorizes advanced practice registered nurses, registered nurses, licensed practical nurses, and licensed clinical laboratory personnel to perform testing at alternate-sites.[17] However, current law does not authorize registered nurses or laboratory technicians to perform alternate-site testing within a freestanding emergency department.

Freestanding Emergency Departments

A freestanding emergency department (FED) is a facility that receives individuals for emergency care and is physically separate from a hospital.[18]

In Florida, any licensed hospital with a dedicated emergency department may provide emergency services in a location separate from the hospital's main premises.[19] AHCA interprets existing law to allow a licensed hospital to establish and operate a FED as part of facility operations, similar to other hospital outpatient departments, without a separate license.[20] There are no separate rules or standards specific to FEDs; rather, existing laws and rules for hospital emergency departments apply to them.

[14] Section 464.003(19), F.S.
[15] Section 464.019(1)(b), F.S., and Rule 64B9-2.021, F.A.C.
[16] Rule 59A-3.242, F.A.C.
[17] Rule 59A-3.242(1)(g)(6), F.A.C.
[18] There is no single definition of FED, and there are different requirements as well as different names for FEDs depending on which state they are located in.
[19] S. 395.002(22), F.S. Premises means 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.
[20] *See also* The federal Centers for Medicare and Medicaid Services (CMS) refers to these 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; 42 C.F.R. § 413.65(a)(2) and (d)(1) (2017); CMS, *Requirements for Provider-based Off-campus Emergency Departments* (Jan. 11, 2008), available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS1207239 (last visited March 8, 2022).

Since 2016, the number of FEDs in Florida increased 45 percent, while the number of visits to FEDs increased by 83 percent.[21] Currently, 96 FEDs operate under the licenses of 61 hospitals.[22]

Effect of the Bill

Clinical Laboratory Personnel

CS/HB 931 exempts registered nurses (RNs) from clinical laboratory personnel licensure requirements. This authorizes RNs to perform moderate-level or waiver-level clinical laboratory testing within a hospital or a hospital-based off-campus emergency department that is separately certified by the Clinical Laboratory Improvement Amendments under federal law. The bill requires the laboratory director of the hospital or hospital-based off-campus emergency department to determine if the RN is qualified to perform such testing.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[21] Florida Agency for Health Care Administration, FloridaHealthFinder.gov, Data Summaries and Reports, *Emergency Department Visits and Admissions by Facility 2016-219,* available at https://www.floridahealthfinder.gov/researchers/QuickStat/quickstat.aspx (last visited March 8, 2022).
[22] Florida Agency for Health Care Administration, Hospital and Outpatient Services Unit, *List of Florida Licensed Hospitals with Off-site Emergency Departments as of March 8, 2022,* available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Reports.shtml (last visited March 8, 2022).