

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	18 Y, 0 N, As CS	Morris	McElroy
2) Health & Human Services Committee	20 Y, 0 N	Morris	Calamas

SUMMARY ANALYSIS

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. 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. 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. With limited exceptions, including certain laboratories and health care practitioners, only licensed clinical laboratory personnel may perform clinical laboratory testing.

Generally, a hospital's main or central laboratory, or satellite laboratories that are certified by federal law established on the same or adjoining grounds of a licensed hospital, may perform clinical laboratory testing. Current law 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 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 room or the emergency room, or anywhere else under the administrative control of a hospital. Current Agency for Health Care Administration (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 facility that receives individuals for emergency care and is structurally separate from a hospital. Only licensed clinical laboratory personnel may perform clinical laboratory testing in a FED.

CS/HB 931 exempts registered nurses who perform alternate-site testing within a hospital or a hospital-based off-campus emergency department from clinical laboratory personnel licensure requirements. This allows registered nurses to perform alternate-site testing within a FED.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Clinical Laboratories

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.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 Clinical Laboratory Improvement Amendments of 1988 (CLIA) program under federal law.³

Clinical Laboratory Personnel

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.⁴

Current law provides exemptions from the application of part I of ch. 483, F.S., which regulates clinical laboratory personnel. Exemptions include:⁵

- 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

¹ Section 483.803, F.S.

² Ss. 483.803(2)(a)-(c), F.S.

³ Section 395.009(1), F.S.

⁴ Section 483.809, F.S. and ch. 64B3-5, F.A.C.

⁵ Section 483.801, F.S.

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.⁶

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.⁷ 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.⁸

Currently, registered nurses licensed under ch. 464, F.S., are not exempt from clinical laboratory personnel regulation.

Alternate-Site Laboratory Testing

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.⁹ 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 Agency for Health Care Administration (AHCA) rule authorizes advanced practice registered nurses, registered nurses, licensed practical nurses, and licensed clinical laboratory personnel to perform testing at alternate-sites.¹⁰ 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 structurally separate from a hospital.¹¹ 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.¹²

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.¹³ There are no additional rules or standards specific for FEDs; in fact, the term FED is not currently defined in statute or rule. 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. However, a hospital that wishes to establish a FED is required to get approval from AHCA’s Office of Plans and Construction.¹⁴

⁶ Section 464.006, F.S.

⁷ Section 464.003(19), F.S.

⁸ Section 464.019(1)(b), F.S., and Rule 64B9-2.021, F.A.C.

⁹ Rule 59A-3.242, F.A.C.

¹⁰ Rule 59A-3.242(1)(g)(6), F.A.C.

¹¹ 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.

¹² 42 C.F.R. § 413.65(a)(2) and (d)(1) (2017). See also 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 Jan. 21, 2022).

¹³ 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.

¹⁴ Rule 59A-3.066(2)(e), F.A.C.

Since 2016, the number of FEDs in Florida increased 45 percent, while the number of visits to FEDs increased by 83 percent.¹⁵ Currently, 96 FEDs operate under the licenses of 61 hospitals.¹⁶

Effect of the Bill

Clinical Laboratory Personnel

CS/HB 931 exempts registered nurses who perform alternate-site testing within a hospital or a hospital-based off-campus emergency department from clinical laboratory personnel regulation under part I of ch. 483, F.S. This allows registered nurses to perform alternate-site testing within a FED.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 483.801, F.S., relating to exemptions.

Section 2: 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.

¹⁵ Florida Agency for Health Care Administration, FloridaHealthFinder.gov, Data Summaries and Reports, *Emergency Department Visits and Admissions by Facility 2016-2019*, available at <https://www.floridahealthfinder.gov/researchers/QuickStat/quickstat.aspx> (last visited Jan. 21, 2022).

¹⁶ Florida Agency for Health Care Administration, Hospital and Outpatient Services Unit, *List of Florida Licensed Hospitals with Off-site Emergency Departments as of Jan. 3, 2022*, available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Reports.shtml (last visited Jan. 21, 2022).

D. FISCAL COMMENTS:

None.

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:

Current law provides sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On January 25, 2022, the Professions and Public Health Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment authorizes registered nurses to conduct alternate-site testing in freestanding emergency departments.

This analysis is drafted to the committee substitute as passed by the Professions and Public Health Subcommittee.