

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 655 Clinical Laboratories
SPONSOR(S): Health Quality Subcommittee; Roberson
TIED BILLS: **IDEN./SIM. BILLS:** SB 738

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 0 N, As CS	Guzzo	O'Callaghan
2) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

A clinical laboratory is a location in which body fluids or tissues are analyzed for purposes of the diagnosis, assessment, or prevention of a medical condition. Clinical laboratories may be free-standing facilities, may be part of a hospital, or may be part of a private practitioner's office. Current law authorizes physicians, chiropractors, podiatrists, naturopaths, optometrists, and dentists to operate their own clinical laboratories, called "exclusive use" laboratories, to exclusively diagnose and treat their own patients.

Clinical laboratories are required to accept and examine human specimens submitted by certain practitioners if the specimen and test are typically performed by the lab.

A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by a practitioner. Clinical laboratories are prohibited from charging different prices for tests based upon the chapter under which a practitioner is licensed.

The bill requires a clinical laboratory to make its services available to specified licensed health care practitioners, instead of requiring the laboratory to accept a human specimen from such practitioners. The bill also deletes a provision in current law that only authorizes a clinical laboratory to refuse a specimen if there has been a history of nonpayment.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides that the act will take effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Clinical Laboratories

Licensure

A clinical laboratory is a location in which body fluids or tissues are analyzed for purposes of the diagnosis, assessment, or prevention of a medical condition.¹ Clinical laboratories are licensed and regulated by the Agency for Health Care Administration (AHCA), pursuant to part I of chapter 483, F.S., and Rule 59A-7, F.A.C. Clinical laboratories may be free-standing facilities, may be part of a hospital, or may be part of a private practitioner's office.² A clinical laboratory license may only be issued to a laboratory to perform procedures and tests that are within the specialties or subspecialties in which the laboratory personnel are qualified to perform.³ There are 3,761 actively licensed clinical laboratories in Florida.⁴ Certain clinical laboratories are exempt from licensure, including clinical laboratories:

- Operated by the federal government;
- Operated and maintained exclusively for research and teaching purposes that do not involve patient or public health services; and
- Performing only "waived tests".⁵

Acceptance, Collection, Identification, and Examination of Specimens

A clinical laboratory may only examine human specimens at the request of a licensed practitioner.⁶ Section 483.181(5), F.S., requires clinical laboratories to accept and examine human specimens submitted by certain practitioners if the specimen and test are typically performed by the laboratory. Specifically, clinical laboratories must accept and examine specimens submitted by a:

- Physician;
- Chiropractor;
- Podiatrist;
- Naturopath;
- Optometrist;
- Dentist; or an
- Advanced registered nurse practitioner.⁷

A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by a practitioner. Clinical laboratories are prohibited from charging different prices for tests based upon the chapter under which a practitioner is licensed.

Current law authorizes physicians, chiropractors, podiatrists, naturopaths, optometrists, and dentists to operate their own clinical laboratories, called "exclusive use" laboratories, to exclusively diagnose and treat their own patients.⁸ This, however, does not preclude the exclusive use laboratories from also

¹ S. 483.041(2), F.S.

² Id.

³ S. 483.091, F.S.

⁴ AHCA, Florida Health Finder.gov, Facility/Provider Search Results, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (search conducted March 10, 2015).

⁵ S. 483.031, F.S. Examples of waived tests include dip stick urinalysis or tablet reagent urinalysis, fecal occult blood, urine pregnancy tests, erythrocyte sedimentation rate, and blood glucose tests.

⁶ S. 483.181(1), F.S.

⁷ S. 483.181(5), F.S.

⁸ S. 483.035(1), F.S.

being required to accept and examine all specimens submitted by certain practitioners pursuant to s. 483.181(5), F.S.

Administrative Fines and Criminal Penalties

A clinical laboratory is subject to a fine, not to exceed \$1,000, to be imposed by AHCA for each violation of any provision of part I of chapter 483, F.S.⁹ The AHCA must consider certain factors in determining the penalty for a violation, including:

- The severity of the violation, including the probability that death or serious harm to the health or safety of any person could occur as a result of the violation;
- Actions taken by the licensee to correct the violation or to remedy complaints; and
- The financial benefit to the licensee of committing or continuing the violation.¹⁰

In addition to the imposition of fines, an individual may be subject to criminal penalties for a violation of any provision of part I of chapter 483, F.S.¹¹ The AHCA must refer an individual who commits a violation to the local law enforcement agency and the individual may be subject to a misdemeanor of the second degree, punishable as provided in ss. 775.082 and 775.083, F.S.¹² Additionally, AHCA may issue and deliver a notice to cease and desist from such act and may impose, by citation, an administrative penalty not to exceed \$5,000 per act.¹³ Each day that unlicensed activity continues after issuance of a notice to cease and desist constitutes a separate act.¹⁴

An application for licensure or re-licensure as a clinical laboratory may be denied or revoked by AHCA for any violation of part I of chapter 483, F.S.¹⁵

Effect of Proposed Changes

The bill requires a clinical laboratory to make its services available to specified licensed health care practitioners, instead of requiring the laboratory to accept a human specimen from such practitioners. Specifically, a clinical laboratory must make its services available to a:

- Physician;
- Chiropractor;
- Podiatrist;
- Naturopath;
- Optometrist;
- Dentist; or an
- Advanced registered nurse practitioner.

A clinical laboratory may still be subject to fines, criminal penalties and licensure denial or revocation for a violation of this provision or any provision of part I of chapter 483, F.S.

The bill also deletes a provision in current law that only authorizes a clinical laboratory to refuse a specimen if there has been a history of nonpayment.

⁹ S. 483.221(1), F.S.

¹⁰ Id.

¹¹ S. 483.23(1)(a) and (b), F.S.

¹² Id.

¹³ Id.

¹⁴ Id.

¹⁵ S. 408.815(1)(c), F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 483.181, F.S., relating to acceptance, collection, identification, and examination of specimens.

Section 2: Provides that the act shall take effect upon becoming a law.

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.

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:

No additional rulemaking authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 12, 2015, the Health Quality Subcommittee adopted an amendment to the bill and reported the bill favorably as a committee substitute. The amendment:

- Requires clinical laboratories to make their services available to certain practitioners.
- Deletes a provision in current law that only authorizes a clinical laboratory to refuse a specimen if there has been a history of nonpayment.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.