

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 738

INTRODUCER: Senator Grimsley

SUBJECT: Clinical Laboratories

DATE: March 19, 2015

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------|----------------|-----------|--------------------|
| 1. | Looke | Stovall | HP | Pre-meeting |
| 2. | | | FP | |
| 3. | | | RC | |

I. Summary:

SB 738 amends s. 483.181, F.S., to require a clinical laboratory to offer its services to licensed allopathic and osteopathic physicians, chiropractors, podiatrists, naturopaths, optometrists, advanced registered nurse practitioners (ARNP), dentists, and dental hygienists without charging different prices for services based on the license of the practitioner. Clinical laboratories owned by one or more practitioners exclusively for the use of their patients are exempt from this requirement. The bill also allows a clinical laboratory to refuse service if such service is not reimbursable by insurance or by another payor.

II. Present Situation:

Clinical Laboratory 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 of the Florida Administrative Code. 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.² There are 3,760 actively licensed clinical laboratories in Florida.³ 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

¹ Section 483.041(2), F.S.

² Section 483.111, F.S.

³ AHCA, Florida Health Finder.gov, *Facility/Provider Locator*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (search conducted March 10, 2015).

- Performing only “waived tests.”⁴

Acceptance, Collection, Identification, and Examination of Specimens

A clinical laboratory may only examine human specimens at the request of a licensed practitioner or other person licensed to use the findings of clinical laboratory examinations.⁵ 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 (ARNP).⁶

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.⁷ This, however, does not preclude them from also 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 the AHCA, for each violation of any provision of part I of chapter 483, F.S.⁸ 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.⁹

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.¹⁰ The AHCA must refer an individual

⁴ Section 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.

⁵ Section 483.181(1), F.S.

⁶ Section 483.181(5), F.S.

⁷ Section 483.035(1), F.S.

⁸ Section 483.221(1), F.S.

⁹ Id.

¹⁰ Section 483.23(1)(a) and (b), F.S.

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.¹¹ 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.¹² Each day that unlicensed activity continues after issuance of a notice to cease and desist constitutes a separate act.¹³

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.¹⁴

III. Effect of Proposed Changes:

SB 738 amends s. 483.181, F.S., to require a clinical laboratory to offer its services to licensed allopathic and osteopathic physicians, chiropractors, podiatrists, naturopaths, optometrists, ARNPs, dentists, and dental hygienists without charging different prices for services based on the license of the practitioner. Current law requires a clinical laboratory to accept a human specimen from these practitioners. Clinical laboratories owned by one or more practitioners exclusively for the use of their patients are exempt from this requirement.

The bill also allows a clinical laboratory to refuse service if such service is not reimbursable by insurance or by another payor.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

¹¹ Id.

¹² Id.

¹³ Id.

¹⁴ Section 408.815(1)(c), F.S.

B. Private Sector Impact:

SB 738 may have a positive fiscal impact on clinical laboratories if such laboratories are able to refuse service which would not be paid for under the provisions of the bill.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 483.181 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.