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 Fiscal Policy

BILL:	CS/SB 738
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Clinical Laboratories
DATE:	April 8, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Pace	Hrdlicka	FP	**Favorable**
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 738 requires clinical laboratories to make their services available to specified licensed practitioners and prohibits such clinical laboratory from charging different prices for its services based upon the chapter under which a practitioner is licensed. The bill adds a consultant pharmacist or doctor of pharmacy licensed under chapter 465, F.S. to the list of licensed practitioners that a clinical laboratory must serve. The bill repeals limitations on the conditions under which a clinical laboratory may refuse a specimen.

The bill does not have a fiscal impact on state funds.

II. Present Situation:

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 ch. 483, F.S., and Rule Chapter 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

[1] Section 483.041(2), F.S.
[2] Section 483.111, F.S.

are over 3,600 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
- Performing only "waived tests."[4]

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 ch. 483, F.S.[5]

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 ch. 483, F.S.[6] 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.[7]

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 ch. 483, F.S.[8]

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.[9] 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)[10].

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[3] AHCA, Florida Health Finder.gov, *Facility/Provider Locator*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (search conducted April 6, 2015).
[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 408.815(1)(c), F.S.
[6] Section 483.221(1), F.S.
[7] Id.
[8] Section 483.23(1)(a)4. and (b), F.S. A violation constitutes a second degree misdemeanor.
[9] Section 483.181(1), F.S.
[10] Section 483.181(5), F.S.

Currently, a clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by a practitioner.[11] Clinical laboratories are prohibited from charging different prices for tests based upon the chapter under which a practitioner is licensed.[12]

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.[13] 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.

III. Effect of Proposed Changes:

The bill amends s. 483.041, F.S., to add consultant pharmacists and doctors of pharmacy to the definition of "licensed practitioner." A clinical laboratory will be able to examine human specimen at the request of a licensed consultant pharmacist or doctor of pharmacy.

The bill requires a clinical laboratory to offer its services to licensed allopathic and osteopathic physicians, chiropractors, podiatrists, naturopaths, optometrists, ARNPs, dentists, dental hygienists, consultant pharmacists, and doctors of pharmacy without charging different prices for services based on the license of the practitioner.

The bill repeals the limitation on the requirement of a clinical laboratory to offer services if the specimen and the test are typically performed by the laboratory. The bill also repeals the limitation on a clinical laboratory to only refuse a specimen based on a history of nonpayment for services by the practitioner submitting a specimen. As a result, a clinical laboratory may refuse a specimen for reasons such as having inadequate equipment or resources for a particular test or because a particular test is not reimbursable under the applicable insurance policy and the practitioner has not made other arrangements for payment.

This bill is effective upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The mandate restrictions do not apply because the bill does not require counties and municipalities to spend funds, reduce counties' or municipalities' ability to raise revenue, or reduce the percentage of a state tax shared with counties or municipalities.

B. Public Records/Open Meetings Issues:

None.

[11] Section 438.181(5), F.S.
[12] Id.
[13] Section 483.035(1), F.S.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill 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.

Additionally, a consultant pharmacist or doctor of pharmacy may be able to request services from a clinical laboratory.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 483.041 and 483.181.

IX. Additional Information:

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

CS by Health Policy on March 23, 2015.
The CS amends SB 768 to add consultant pharmacists and doctors of pharmacy to the definition of "licensed practitioner" under s. 483.041, F.S., to add consultant pharmacists and doctors of pharmacy to the list of practitioners to whom a clinical laboratory must make its services available, and to remove language specifying when a clinical laboratory may refuse to provide its services.

B. Amendments:

None.