HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/HB 655	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Health Quality Subcommittee; Roberson	113 **Y's**	0 **N's**
COMPANION BILLS:	CS/SB 738	**GOVERNOR'S ACTION:**	Pending

SUMMARY ANALYSIS

CS/CS/HB 655 passed the House on April 16, 2015, and subsequently passed the Senate on April 27, 2015.

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.

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 authorizes a clinical laboratory to refuse a specimen only if there has been a history of nonpayment.

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

Subject to the Governor's veto powers, the effective date of this bill is upon becoming a law.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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.

[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.

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.[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 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]

Consultant Pharmacists and Doctors of Pharmacy

A consultant pharmacist is a pharmacist who is paid to provide expert advice on the use of medications by individuals or within institutions, or on the provision of pharmacy services to institutions.[15] In order to be licensed as a consultant pharmacist, an individual must:

- Hold an active license as a pharmacist;
- Successfully complete a consultant pharmacist course of at least 12 hours;[16] and
- Successfully complete a period of assessment and evaluation under the supervision of a preceptor.[17]

A consultant pharmacist may order and evaluate clinical laboratory testing for a patient residing in a nursing home upon authorization by the medical director of the nursing home.[18]

Consultant pharmacists and pharmacists holding a Doctor of Pharmacy degree may order and evaluate clinical laboratory testing for individuals under the care of a licensed home health agency, if authorized by a licensed physician, osteopath, podiatrist, or dentist.[19]

Effect of the Bill

[8] S. 483.221(1), F.S.
[9] Id.
[10] S. 483.23(1)(a) and (b), F.S.
[11] Id.
[12] Id.
[13] Id.
[14] S. 408.815(1)(c), F.S.
[15] American Society of Consultant Pharmacists, *FAQs,* available at: https://www.ascp.com/articles/about-ascp/frequently-asked-questions (last viewed March 20, 2015).
[16] Rule 64B16-26.300(3)(b), F.A.C., requires the course to be sponsored by an accredited college of pharmacy located within the State of Florida, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C.
[17] S. 465.003(3), F.S., and Rule 64B16-26(3), F.A.C.
[18] S. 465.0125(1), F.S.
[19] S. 465.0125(2), F.S.

Current law requires a clinical laboratory to accept a human specimen submitted for examination by certain practitioners if the specimen and test are the type performed by the clinical laboratory.

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 adds consultant pharmacists and doctors of pharmacy to the list of practitioners that a clinical laboratory must avail its services. The bill also deletes a provision in current law that authorizes a clinical laboratory to refuse a specimen only if there has been a history of nonpayment by the submitting practitioner.

The bill makes a conforming change by amending the definition of "licensed practitioner" as it is used in part I of chapter 483, F.S., to mean a consultant pharmacist or doctor of pharmacy licensed under chapter 465, F.S.

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.