

**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.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: CS/SB 738

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Clinical Laboratories

DATE: March 23, 2015

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	<b>Fav/CS</b>
2.			FP	
3.			RC	

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 738 amends ss. 483.041 and 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, dental hygienists, consultant pharmacists, and doctors of pharmacy without charging different prices for services based on the license of the practitioner and adds consultant pharmacists and doctors of pharmacy to the definition of “licensed practitioner.” The bill also strikes the limitation on the conditions under which a clinical laboratory may refuse a specimen. Under current law, the only reason for which a clinical laboratory may deny testing a specimen is based on a history of nonpayment for services by the practitioner submitting the specimen. This bill allows a clinical laboratory to decline testing for other reasons as well.

The bill takes effect upon becoming law.

**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.<sup>1</sup> Clinical laboratories are licensed and regulated by the Agency for Health Care Administration (AHCA), pursuant to part I of

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<sup>1</sup> Section 483.041(2), F.S.

ch. 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.<sup>2</sup> There are 3,760 actively licensed clinical laboratories in Florida.<sup>3</sup> 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.”<sup>4</sup>

### **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.<sup>5</sup> 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)<sup>6</sup>.

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.<sup>7</sup> 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.

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<sup>2</sup> Section 483.111, F.S.

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

<sup>4</sup> 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.

<sup>5</sup> Section 483.181(1), F.S.

<sup>6</sup> Section 483.181(5), F.S.

<sup>7</sup> Section 483.035(1), 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 ch. 483, F.S.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup> Each day that unlicensed activity continues after issuance of a notice to cease and desist constitutes a separate act.<sup>13</sup>

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.<sup>14</sup>

### **III. Effect of Proposed Changes:**

CS/SB 738 amends s. 483.041, F.S., to add consultant pharmacists and doctors of pharmacy to the definition of “licensed practitioner” for Part I of ch. 483, F.S., related to clinical laboratories and 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, dental hygienists, consultant pharmacists, and doctors of pharmacy without charging different prices for services based on the license of the practitioner. The bill also strikes language stating that a clinical laboratory may only refuse a specimen based on a history of nonpayment for services by the practitioner submitting the specimen. As a consequence of this change, a clinical laboratory may refuse a specimen for other 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.

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<sup>8</sup> Section 483.221(1), F.S.

<sup>9</sup> Id.

<sup>10</sup> Section 483.23(1)(a) and (b), F.S.

<sup>11</sup> Id.

<sup>12</sup> Id.

<sup>13</sup> Id.

<sup>14</sup> Section 408.815(1)(c), F.S.

**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.

**B. Private Sector Impact:**

CS/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 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.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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