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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE STANDARDS & REGULATORY REFORM
BILL RESEARCH & ECONOMIC IMPACT STATEMENT

BILL #: HB 1115

RELATING TO: Clinical Laboratory Personnel

SPONSOR(S): Representative Saunders

STATUTE(S) AFFECTED: Chapter 483, Parts I and IV, F.S.; Section 408.033, F.S.

COMPANION BILL(S): CS/SB 2142(c), CS/SB 270(s)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:
(1) HEALTH CARE STANDARDS & REGULATORY REFORM YEAS 7 NAYS 0
(2) HEALTH & HUMAN SERVICES APPROPRIATIONS
(3)
(4)
(5)

I. SUMMARY:

The bill exempts laboratories operated by practitioners for the exclusive use of their own patients (exclusive use physicians office laboratories) from the health care facility assessment that funds the local and statewide health councils.

It removes the requirement that applications for clinical laboratory licenses be made under oath, and eliminates the authority for the agency to collect licensure fees for clinical laboratories.

The bill also eliminates clinical laboratory personnel licensure requirements for exclusive use physician offices. Additionally, it specifies the qualifications for clinical laboratory directors.

The bill has a fiscal impact of over $900,000 (annualized at $450,000). There is no fiscal impact on local government or the private sector.

II. SUBSTANTIVE RESEARCH:

A. PRESENT SITUATION:

During the 1993 legislative session, the provisions of part I of chapter 483, F.S., the Florida Clinical Laboratory Law, were reviewed subject to the Sunset Review Act. In most sunset reviews, the question is whether a particular profession, business, industry, or other endeavor should or should not continue to be regulated by the state. With the clinical laboratory review, a third option was to cease state regulation and in so doing have the responsibility for clinical laboratory regulation revert to the federal government. Given Florida's extensive history with laboratory regulation, the Legislature concluded that the state should continue to regulate clinical laboratories and in continuing this regulation, the Legislature made changes to assure that state law conformed to the then recent federal law and regulatory revisions.

Part I of chapter 483, F.S., provides for clinical laboratory regulation by the Agency for Health Care Administration (AHCA). Created as part of the 1993 Sunset Review bill, s. 483.035, F.S., provides the authorization for exclusive use physician office laboratories, when physicians perform tests on their own patients. For such laboratories, AHCA is to adopt rules for staffing, proficiency testing, and construction standards based upon and not exceeding the standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and federal regulations adopted thereunder. To accompany this language, the 1993 enactment also created s. 483.811(3), F.S., to authorize the Board of Clinical Laboratory Personnel to adopt rules for the licensure, education, and training of personnel in physician office laboratories operated under s. 483.035, F.S., based on and not exceeding standards contained in CLIA '88.

Section 483.101, F.S., provides the requirement that an owner or operator or public official responsible for a clinical laboratory submit, under oath, an application for licensure upon forms provided by the agency. Section 483.106, F.S., provides a similar requirement for those seeking a certificate of exemption from laboratory licensure.

There are presently in excess of 9,000 licensed clinical laboratories in Florida, which include hospital laboratories, independent laboratories, and physician offices that perform laboratory testing. All such clinical laboratories are required to renew their licenses every two years, currently all due for renewal October 1, 1997. The licensure fee is set statutorily, and is $100 biennially. The agency indicates that the $100 fee is inadequate to cover the cost of regulation, which includes processing of an application, statutorily required survey (inspection) of the laboratory premises, and any complaint investigations during the licensure period.

CLIA is a federal regulatory program that requires every clinical laboratory in the nation to comply with federal regulatory standards. CLIA is administered by the Health Care Financing Administration (HCFA) through contracts with individual state agencies. AHCA is the state agency that administers the CLIA program for HCFA in the State of Florida. Clinical laboratories are charged a fee for processing CLIA applications and conducting CLIA surveys. This fee is in addition to the $100 state licensure fee. CLIA fees collected by HCFA are not returned in total to the agency for administration of the program, and the current CLIA budget award to AHCA is insufficient to cover the cost of regulatory activities.

The federal CLIA regulations allow state regulatory licensure programs to apply for exempt status if the state's program standards are judged to be equivalent to or more stringent than the CLIA program requirements. Florida's laboratory licensure regulations are equal to the CLIA regulations. When exempt status is granted, laboratories will no longer be required to pay the applicable state licensure fees in lieu of CLIA fees. Without CLIA exempt status, clinical laboratories are subject to duplicate state and federal fees. At such time as exempt status is granted, clinical laboratories will pay a higher licensure fee, in an amount that CLIA currently charges, but be subject to only one application and survey process. In effect, when "exempt status" is granted, the total fees paid by clinical laboratories will be reduced by the current $100 licensure fee. AHCA is currently developing an application to submit to HCFA for exempt status for the State of Florida.

In order for a state to apply for exempt status, it must submit evidence to HCFA that the state licensure program is equal to or exceeds CLIA requirements. This exempt status is not permanent. Exempt status is granted for a specific negotiated period, typically from two to six years. Each state seeking exempt status must also pay a fee to CLIA before exempt status is granted. This fee is payable to HCFA in advance, and is negotiable at the beginning of each term. In the past HCFA has accepted incremental payments from states granted exempt status. An application for CLIA exempt status is being prepared by the agency. After this application is made, final HCFA approval cannot be expected until early to mid 1998. The statute provides for an increase in fees at such time as Florida receives "exempt status" from CLIA.

Part IV of chapter 483, F.S., provides the requirements for the Board of Clinical Laboratory Personnel. Section 483.811, F.S., provides for approval of laboratory personnel training programs. Section 483.813, F.S., specifies the clinical laboratory personnel licensure requirements. The current clinical laboratory director qualifications are specified in Rule 59O, Florida Administrative Code, but are not specified in statute. Director qualifications as specified in rule include specified education, licensure, and experience. Pursuant to 1996 legislation, the board will be transferred from the agency to the Department of Health on July 1, 1997. The board establishes licensure rules and agency staff administer the licensure application process.

Health care facilities, including clinical laboratories, are assessed an annual fee to fund local and state health planning, under s. 408.033, F.S. For clinical laboratories the annual health planning assessment is $150. Prior to the 1993 Sunset Review of part I of chapter 483, F.S., laboratories operated by five or fewer physicians in their own offices for their own patients only were not licensed and not subject to the health planning assessment. As part of the 1993 Sunset Review rewrite, all physician office laboratories were required to be licensed in order to comply with federal mandates. Exclusive use clinical laboratories were specifically designated as a replacement for the previous "five or fewer" laboratories. The health councils are funded through application fees for certificates of need and by assessments on selected health care facilities and organizations.

Currently, licensure requirements for clinical laboratory personnel extend to personnel in all laboratories except those that hold a Certificate of Exemption pursuant to s. 483.106, F.S. Of those laboratories required to meet laboratory personnel qualifications, approximately 2,200 are physician offices that perform limited laboratory testing exclusively for their own patients (they do not take referrals for testing other physicians'

patients). Because the laboratory testing is limited in these offices and under the direct supervision of the physician, there has been much discussion about the necessity of requiring personnel in such physician's offices to be subject to personnel licensure requirements, as are personnel in larger laboratory that perform more complex tests.

Part V of chapter 468, F.S., is the "Respiratory Care Act". Existing legislative intent language contained in s. 468.352, F.S., specifies that "it is the intent of the Legislature that personnel certified or registered pursuant to this part shall be exempt from the licensure provisions of chapter 483, F.S.

B. EFFECT OF PROPOSED CHANGES:

The bill exempts exclusive use clinical laboratories regulated under s. 483.035, F.S., from the annual $150 health planning assessment. Licensure provisions for personnel performing laboratory testing in the exclusive use physician's offices are eliminated.

The requirement that clinical laboratory license applications be made under oath is eliminated.

Relating to exclusive use clinical laboratories, education and training of personnel elements are added to the rulemaking elements of the agency.

The agency is authorized to conduct either on-site or off-site inspections.

Clinical laboratories are no longer subject to a biennial state licensing fee of $100 after July 1, 1997.

Eliminates the licensure requirement for those persons performing clinical laboratory testing in exclusive use physician offices.

The Board of Clinical Laboratory Personnel no longer has the authority to promulgate rules relating to the qualifications of clinical laboratory directors. A director now must have four years of clinical laboratory experience with two years experience in the specialty to be directed or be nationally board-certified in the specialty to be directed, and must either: be a physician licensed under chapter 458 or 459, F.S.; hold an earned doctoral degree in chemical, physical, or biological science from an accredited institution; or, for the subspecialty of oral pathology, be a physician licensed under chapter 458 or 459, F.S., or be a dentist licensed under chapter 466, F.S.

C. APPLICATION OF PRINCIPLES:

1. <u>Less Government:</u>

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

The bill reduces the Board of Clinical Laboratory Personnel regulatory authority by eliminating their regulation of exclusive use physician office personnel.

It reduces the regulation of those persons performing clinical laboratory testing in exclusive use physician offices. The elimination of this licensure requirement gives the physician the flexibility and latitude in providing training of his or her staff. The physician will be liable for the staff's performance.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

The bill requires the shifting of regulatory costs to a source other than the regulated entity. Although regulatory fees are eliminated, statutory regulatory activities remain.

(3) any entitlement to a government service or benefit?

No.

b. If an agency or program is eliminated or reduced:

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

The bill requires the shifting of regulatory costs to a source other than the regulated entity.

(2) what is the cost of such responsibility at the new level/agency?

The cost shift would be approximately $450,000 annually, over and above the current program deficit of approximately $500,000.

(3) how is the new agency accountable to the people governed?

Not Applicable.

2. <u>Lower Taxes:</u>

a. Does the bill increase anyone's taxes?

No.

b. Does the bill require or authorize an increase in any fees?

No.

c. Does the bill reduce total taxes, both rates and revenues?

No.

d. Does the bill reduce total fees, both rates and revenues?

Yes. The bill reduces the fees paid by clinical laboratories, by eliminating the authority to collect the $100 biennial laboratory licensure fee. It also eliminates the $150 annual assessment on exclusive use physician offices for the funding of state and local health councils.

e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No. The bill contradicts the public policy of fee supported regulation and shifts responsibility for funding of clinical laboratory regulation to sources other than the regulated entity.

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

The elimination of the licensure requirements for exclusive use physician office clinical laboratory testing personnel gives the physician the flexibility and latitude in providing training of his or her staff, while it continues to hold the physician liable for the staff's performance.

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

No.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

N/A

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. SECTION-BY-SECTION RESEARCH:

Section 1. Amends s. 408.033(a), F.S., relating to the funding of local and state health planning, to exempt exclusive use clinical laboratories regulated under s. 483.035, F.S., from the annual $150 health planning assessment.

Section 2. Amends s. 483.035(1), F.S., relating to exclusive use clinical laboratories, to add to the agency rulemaking authority elements relating to personnel, including education and training of personnel.

Section 3. Amends s. 483.101, F.S., to eliminate the requirement for clinical laboratory license applications be made under oath.

Section 4. Amends. s. 483.801, F.S., to eliminate the requirement for clinical laboratory license applications be made under oath.

Section 5. Amends s. 483.172(4), F.S., relating to clinical laboratory licensing fees, to specify that clinical laboratories are no longer subject to a biennial state licensing fee of $100 after July 1, 1997.

Section 6. Amends s. 483.801, F.S., relating to exemptions from licensure requirements for clinical laboratories and clinical laboratory personnel, to indicate that persons engaged in testing at laboratories regulated under s. 583.035(1), F.S., exclusive use clinical laboratories, and under s. 483.031(2), F.S., laboratories limited to waived tests, are exempt from clinical laboratory personnel licensure requirements. In addition, those respiratory therapists and respiratory care practitioners certified or registered under part V of chapter 468, F.S., are also exempt from clinical laboratory personnel licensure requirements.

Section 7. Amends s. 483.803(3), F.S., to exclude from the definition of “clinical laboratory personnel:” persons engaged in testing at laboratories regulated under s. 483.035(1), F.S., exclusive use clinical laboratories or 483.031(2), F.S., laboratories limited to waived tests.

Section 8. Amends s. 483.811(3), F.S., relating to the duties of the Board of Clinical Laboratory Personnel regarding training program approval, to delete reference to the board’s duties for the licensure, education, and training of personnel in physician office laboratories regulated under s. 483.035, F.S.

Section 9. Amends s. 483.813, F.S., relating to the applicability of the laboratory personnel licensure provisions, to indicate that the provisions do not apply to persons engaged in testing at laboratories regulated under s. 483.035(1), F.S., exclusive use clinical laboratories, or under s. 483.031(2), F.S., laboratories performing only waived tests.

Section 10. Creates s. 483.824, F.S., to specify in statute the qualifications of a clinical laboratory director. A director must have four years of clinical laboratory experience with two years experience in the specialty to be directed or be nationally board certified in the specialty to be directed, and must either: be a physician licensed under chapter 458 or 459, F.S.; hold an earned doctoral degree in chemical, physical, or biological science form an accredited institution; or, for the subspecialty of oral pathology, be a physician licensed under chapter 458 or 459, F.S., or be a dentist licensed under chapter 466, F.S.

Section 11. Provides for the bill to take effect upon becoming a law.

III. FISCAL RESEARCH & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

FISCAL IMPACT ON AHCA:

1. Non-recurring Effects:

Health Care Trust Fund
Program Entity: Health Facility Regulation
Program Category: Health Care Quality Improvement

	FY 97-98	FY 98-99
Non-recurring effects	None	None

2. Recurring Effects:

Revenues		
License Fees	$0	$0
CLIA Budget Award	$763,000	$763,000
Expenditures	$1,700,000	$1,700,000

3. Long Run Effects Other Than Normal Growth:

The agency indicates that “loss of the ability to collect the $100 biennial licensure fee for clinical laboratory licensure will result in the loss of over $900,000 in fees biennially (annualized at $450,000). With the loss of license revenue, the only revenue generated for regulatory activities is the federal CLIA budget award. The agency administers the federal CLIA program for HCFA. A budget award of $763,000 was awarded for fiscal year 1996-97. The amount of the budget awards has decreased over the past two years, and has not covered the state’s actual cost to administer the CLIA program. Information from HCFA indicates that CLIA fees are likely to increase in the near future. Even though these fees are likely to be

raised, there is no guarantee that these increased fees will translate into higher budget awards to the states for CLIA program administration."

The agency also indicates "fiscal analysis of the effects of the loss of licensure fee revenue indicate an annualized deficit of over $900,000 if licensure fees are lost and assuming that future expenditures and CLIA budget awards remain stable."

4. Total Revenues and Expenditures:

	FY 97-98	FY 98-99
License Fees	$0	$0
CLIA Budget Award	$$763,000	$763,000
Expenditures	$1,700,000	$1,700,000
Total Revenue Loss	($937,000)	($937,000)

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

The agency indicates that "the local health planning council fee is not being collected from the exclusive use physician at this time. The loss of this will result in a potential loss of approximately $500,000 annually. Collections from other providers subject to s. 408.033, F.S., has been sufficient to meet the funding needs of the health councils.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

Those impacted by other fees deposited to the Health Care Trust Fund will be impacted by the cost shift needed to cover the administration of the clinical laboratory regulatory activities.

2. Direct Private Sector Benefits:

The elimination of the clinical laboratory fee would benefit the private sector by eliminating the $100 biennial clinical laboratory license fee and the $150 annual assessment for health planning councils.

3. Effects on Competition, Private Enterprise and Employment Markets:

None.

D. FISCAL COMMENTS:

The Agency for Health Care Administration indicates that "the loss of licensure fees may result in an increase in the annualized deficit of $450,000 in revenue needed for clinical laboratory regulatory activity, because workload is not reduced by the bill. Funds will need to be shifted from other sources to replace these revenue collections. CLIA budget award amount for 1997-98 assumes there will be no decrease in award level.

No data regarding the fiscal impact of the loss of revenue from the licensure of the Exclusive Use Technician was available from the Board of Clinical Laboratory Personnel."

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

The **Florida Coalition of Professional Laboratory Organizations, Inc.** indicates that they oppose the bill.

The **Florida Medical Association** indicates that they support the bill.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

Three amendments were placed on the bill.

Amendment One was a strike everything amendment to conform HB 1115 to CS/SB 270. New elements include:

Exempts exclusive use clinical laboratories from paying the annual $150 health planning ass;

Authorizes AHCA to conduct on-site or off-site clinical laboratory inspections;

Reinstates the requirement that applications for clinical laboratory licensure and certificates of exemption be submitted under oath;

Includes experience requirements for clinical laboratory directors; and

Extends the authority to collect fees until July 1, 1998.

Amendment One to the Amendment provides “anti-discrimination” language, requiring laboratories to accept specimens from any practitioner and specifies that laboratories shall charge the same price for everyone.

Amendment Two to the Amendment was a technical amendment to ensure that doctoral degrees in chemical, physical, or biological science are earned from a **regionally** accredited institution.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE STANDARDS & REGULATORY REFORM:

Prepared by:	Legislative Research Director:
Terri L. Paddon	Robert W. Coggins