STORAGE NAME: h0673s1.hcl
DATE: March 13, 2000

HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
ANALYSIS

BILL #: CS/HB 673

RELATING TO: Health Insurance/Clinical Laboratory Services

SPONSOR(S): Committee on Health Care Licensing & Regulation and Representative Posey

TIED BILL(S):

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH CARE LICENSING & REGULATION YEAS 12 NAYS 1
(2) INSURANCE
(3) GENERAL GOVERNMENT APPROPRIATIONS
(4)
(5)

I. SUMMARY:

Committee Substitute for HB 673 provides that losing or misplacing a specimen is grounds for which disciplinary actions may be taken against a clinical laboratory. The bill requires clinical laboratories to report any incident of a lost or misplaced specimen to the Agency for Health Care Administration (AHCA) and to the referring physician. Also, this bill provides that disciplinary actions may be taken against any physician who fails to report to AHCA any laboratory licensed under chapter 483, F.S., that is in violation of this chapter.

CS/HB 673 provides that laboratories which perform anatomic pathology must be staffed by a physician certified in anatomic pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or possessing qualifications that are equivalent to those required for such qualification. Laboratories that perform dermatopathology must be staffed by a physician certified in anatomic pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or certified in dermatopathology by the American Board of Pathology and the American Board of Pathology, or certified in dermatology by the American Board of Dermatology, or possessing qualifications equivalent to those required to gain one of the preceding certifications.

The bill will have a fiscal impact on AHCA of $58,478 the first year and $53,179 each following year.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No []	N/A [x]
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No []	N/A [x]
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

For any principle that received a "no" above, please explain:

B. PRESENT SITUATION:

According to the Agency for Health Care Administration (AHCA), there are nearly 11,000 clinical laboratories licensed by the State of Florida. Approximately 9,300 of those licensed facilities are found in physician office settings, nursing homes, home health agencies or other related health care facilities and perform only waived or simple microscopic tests. The remaining 1,700 facilities are traditional clinical laboratories that perform more complex testing, and are located in larger physician office practices, hospitals and reference laboratories.

Clinical laboratories in Florida are licensed by AHCA pursuant to Part I, chapter 483, F.S. Section 483.111, F.S., states that "a license may be issued to a clinical laboratory to perform only those clinical laboratory procedures and tests that are within the specialties and subspecialties in which the clinical laboratory personnel are qualified."

Clinical laboratory personnel are licensed by the Department of Health pursuant to Part III, chapter 483, F.S. Section 483.823, F.S., states that the Board of Clinical Laboratory Personnel shall prescribe minimum qualifications for clinical laboratory personnel. Section 483.824, F.S., requires that clinical laboratory directors have four years of clinical laboratory experience with two years of experience in the specialty to be directed. Certification in the specialty to be directed, by a national board, may substitute for the two years' experience. Additionally, the director must be a physician licensed pursuant to either chapter 458 or 459, F.S., or hold an earned doctoral degree in a chemical, physical, or biological science and be nationally certified.

Recently, the Florida Society of Dermatologists brought to the Legislature concerns about the quality of pathology reports being obtained through their HMOs. The dermatologists are concerned that too many specimens are being lost or misdiagnosed. They would prefer selecting the clinical laboratory that does the analysis of patient tissue samples.

C. EFFECT OF PROPOSED CHANGES:

The bill provides that losing or misplacing a specimen is grounds for which disciplinary actions may be taken against a clinical laboratory. Clinical laboratories must report any incident of a lost or misplaced specimen to the Agency for Health Care Administration (AHCA) and to the referring physician. Also, the bill provides that disciplinary actions may

be taken against any physician who fails to report to AHCA any laboratory licensed under chapter 483, F.S., that is in violation of this chapter.

CS/HB 673 provides that laboratories which perform anatomic pathology must be staffed by a physician certified in anatomic pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or possessing qualifications that are equivalent to those required for such qualification. Laboratories that perform dermatopathology must be staffed by a physician certified in anatomic pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or certified in dermatopathology by the American Board of Pathology and the American Board of Pathology, or certified in dermatology by the American Board of Dermatology, or possessing qualifications equivalent to those required to gain one of the preceding certifications.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 458.331, F.S., to provide that any physician licensed under this chapter, who fails to report to AHCA any clinical laboratory licensed under chapter 483 that is in violation of that chapter, may be subject to disciplinary actions.

Section 2. Amends s. 459.015, F.S., to provide that any physician licensed under this chapter, who fails to report to AHCA any clinical laboratory licensed under chapter 483 that is in violation of that chapter, may be subject to disciplinary actions.

Section 3. Amends s. 483.111, F.S., to require that laboratories which perform certain services must be staffed by physicians with certain certifications.

Section 4. Amends s. 483.181, F.S., to require any clinical laboratory to report to AHCA and to the referring physician any incident of a lost or misplaced specimen.

Section 5. Amends s. 483.201, F.S., to add losing or misplacing specimens to the list of acts which constitute grounds for which disciplinary actions may be taken against a laboratory.

Section 6. Provides an effective date of July 1, 2000.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

	2000-01	2001-02
Agency for Health Care Administration:		
One-Time Expenses		
General Revenue Trust Fund	$5,299	
Recurring Expenses		
General Revenue Trust Fund	$53,179	$53,179
Total Expenses:		
General Revenue Trust Fund	$58,478	$53,179
(1 FTE)		

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

AHCA has indicated that one new FTE is needed to implement the provisions in the bill. The new employee will be assigned to the Clinical Licensure section of the Division of Managed Care and Health Quality to facilitate the reporting of all incidents of specimens lost or misplaced by clinical laboratories.

This committee substitute provides no appropriations.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to expend funds or take 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 revenue in the aggregate.

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

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

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

The Agency for Health Care Administration (AHCA) provided the following concerns:

The performance of anatomic pathology, including dermatopathology is considered the practice of medicine. Existing state medical practice laws and the federal Clinical Laboratory Improvement Amendments (CLIA) currently mandate that anatomic pathology testing be performed by licensed, qualified physicians.

According to AHCA, the proposed new language relating to the staffing requirements for clinical laboratories does not appear to have any practical effect on the currently existing clinical laboratory licensure requirements, since pathologists and dermatopathologists are the only individuals currently authorized to interpret and diagnosis pathology specimens.

The agency is also concerned with the changes made by the bill to s. 483.181, F.S. Clinical laboratories are currently required to inform the person who ordered a test of problems with unsatisfactory specimens. Market forces in the commercial laboratories make communication with their customers regarding problems such as these a necessary business practice.

The term "misplaced" is vague. It is conceivable that specimens could be misplaced, then located and tested without incident or delay. It is unclear if such incidents would be reportable under this language.

The language does not discriminate between specimen types, test complexity, or the locations at which testing is done. Apparently, all licensed laboratories would be required to report. There are approximately 11,000 clinical laboratories licensed by the State of Florida. Nearly 9,300 of these licensed facilities are found in physician office settings, nursing homes, home health agencies or other related health care facilities and perform only waived or simple microscopic tests. The remaining 1,700 facilities are traditional clinical laboratories that perform more complex testing, and are located in larger physician office practices, hospitals and reference laboratories.

Large volume clinical laboratories often process more than one million tests annually. At this volume of specimen receipt, the loss and/or misplacement of some specimens is inevitable. Even a low rate of loss/misplacement will result in a significant number of reporting events. For example a lost/misplaced rate of 1 in every 10,000 would result in

100 reports for every 1,000,000 tests performed (the rate of 1 per 10,000 specimens is for illustration purposes only and is not meant to represent an actual or estimated lost specimen rate).

It is estimated that there are 10 laboratories licensed in Florida that perform over 1 million tests per year. At that rate, these 10 laboratories alone would submit in excess of 1000 reports per year.

The language does not indicate the action that the agency is expected to take in regards to these reports.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

At the February 22, 2000, meeting of the Health Care Licensing & Regulation Committee, a strike-everything amendment to HB 673 was adopted. The bill as amended was approved as a committee substitute.

The original bill required preferred provider, exclusive provider, and health maintenance organization insurers to pay for services at any clinical laboratory without penalty. The bill allowed preferred providers, exclusive providers, and treating physicians to send a specimen to the clinical laboratory of their choice.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:	Staff Director:
Andrew “Andy” Palmer	Lucretia Shaw Collins