HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 53 Clinical Laboratories
SPONSOR(S): Garcia
TIED BILLS: **IDEN./SIM. BILLS:** SB 408

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	5 Y, 0 N	Calamas	Calamas
2)	Health & Family Services Policy Council	25 Y, 0 N, As CS	Lowell	Gormley
3)	Policy Council		Phillips	Hogge
4)				
5)				

SUMMARY ANALYSIS

Currently:

- Each initial and confirmation drug test conducted under the drug-free workplace program requires that the test be conducted by a licensed or certified laboratory;
- Clinical laboratories are required to accept human specimens submitted for examination from specific Florida-licensed licensed practitioners, with the exception of an advanced registered nurse (ARNP). Such practitioners include a; medical physician, physician assistant, osteopathic physician, chiropractic physician, podiatric physician, dentist, and naturopathic physician; and,
- Clinical laboratories may refuse acceptance of such specimen based on a history of nonpayment and must not charge a different price to other licensed health care practitioners.

In effect, the bill:

- Eliminates the requirement that an initial drug test for an employee or job applicant must be conducted by a licensed or certified laboratory under the drug-free workplace program;
- Permits the initial drug test for an employee or job applicant be conducted at the employer's work site under the drug-free workplace program;
- Retains the requirement provided under current law that, if a drug test is positive, a confirmation test must be conducted by a licensed or certified laboratory;
- Requires clinical laboratories include a Florida-licensed ARNP within the current list of Florida-licensed practitioners from whom they must accept human specimens, i.e., blood, tissue and urine, for examination; and,
- Applies the same conditions regarding a clinical laboratory's right to not accept specimens from a specified health care provider based on nonpayment history and the prohibition that a clinical laboratory cannot charge different prices to different health care practitioners for the same service.

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

The bill is effective July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

The bill does not appear to implicate any of the House Principles.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Drug Free Workplace

The requirements for a drug-free workplace are established in section 440.102, F.S. An employer that establishes a drug-free workplace in accordance with this section is eligible for discounts on workers' compensation and employer's liability insurance.[1] In addition, this section states that an employer does not have a legal duty to request an employee or job applicant to undergo drug testing. Lastly, current law requires that each initial drug and confirmation test be conducted by a licensed or certified laboratory.

In a drug-free workplace, an employer must conduct the following types of drug tests:

- Job applicant drug testing;
- Reasonable-suspicion drug testing;
- Routine fitness-for-duty drug testing; and,
- Follow-up drug testing.[2]

In addition, one time only and prior to testing, an employer must provide each employee and job applicant a written policy that contains, among other items, the employer's policy on employee drug use; a confidentiality statement; and the consequences of refusing to submit to a drug test.[3]

Specimen collection and drug testing is governed by various procedures, including:

- The individual's privacy should be considered when collecting a sample;
- The specimen must be documented;
- Collection, storage, and transportation of the specimen should be done to avoid contamination or adulteration of the specimen;
- The person collecting the specimen must collect enough for two drug tests;
- Every specimen producing a positive, confirmed test result must be preserved for 210 days; and,

[1] Section 627.0915, F.S.
[2] Section 440.102(4), F.S.
[3] Section 440.102(3), F.S.

- Initial drug tests and confirmation drug tests must be conducted by a licensed or certified laboratory.[4]

Advanced Registered Nurse Practitioners

Part I of Chapter 464, F.S., the Nurse Practice Act, regulates the profession of nursing. The part provides definitions and requirements for licensed practical nurses, registered nurses, and advanced registered nurse practitioners (ARNPs). The part specifies violations and limits the use of specified titles and abbreviations to only duly licensed or certified nurses who have met certain requirements.

An ARNP is "any person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice."[5] An ARNP must have a master's degree and can be a certified nurse anesthetist, certified nurse midwife, or nurse practitioner.[6] In order to become certified as an ARNP, a nurse must submit an application to the Department of Health demonstrating that he or she has a current license to practice professional nursing and that he or she meets certain requirements set forth by the Board of Nursing. These requirements include:

- Satisfactory completion of a formal post-basic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice;
- Certification by an appropriate specialty board; and,
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.[7]

Additionally, the Board of Nursing requires ARNPs to have a minimum of $100,000/$300,000 (per incident and aggregate, respectively) in medical malpractice insurance.[8]

Under the Nurse Practice Act, an ARNP must perform his or her authorized functions under an established protocol filed with the Board of Nursing.[9] Practitioners licensed in medical practice, osteopathy, or dentistry must supervise the ARNP within the framework of the protocol.[10] The Board of Nursing and the Board of Medicine have promulgated identical administrative rules setting forth standards for the protocols, which establish obligations on medical physicians, osteopathic physicians, and dentists who enter into protocol relationships with ARNPs.[11] The Board of Osteopathic Medicine and the Board of Dentistry are not required to adopt administrative rules regarding the standards for ARNP protocols.

The authorized duties of an ARNP include:

- Monitoring and altering drug therapies;
- Initiating appropriate therapies for certain conditions;
- Ordering and evaluating diagnostic tests;
- Ordering physical and occupational therapy;
- Performing acts of nursing diagnosis and nursing treatment of alterations of the health status; and,
- Performing acts of medical diagnosis and treatment, prescription, and operation.[12]

An ARNP may also perform certain duties within his or her specialty.[13] Although ARNPs may prescribe medications in accordance with the protocol and under the authority of the supervising physician, they cannot prescribe controlled substances.

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[4] Section 440.102(5), F.S.
[5] Section 464.003(7), F.S.
[6] Section 464.012(1)(c), F.S. ARNP applicants graduating on or after October 1, 1998, must have a master's degree for certification. Registered nurse anesthetist applicants graduating on or after October 1, 2001, must have a master's degree.
[7] Section 464.012(1), F.S.
[8] Rule 64B9-4.002, F.A.C.
[9] Section 464.012(3), F.S.
[10] *Id.*
[11] Rules 64B9-4.010 and 64B8-35.002, F.A.C.
[12] Sections 464.012(3) and 464.003(d), F.S.
[13] Section 464.012(4), F.S.

Clinical Laboratories

Clinical laboratories are regulated by Part I, Chapter 483, F.S., administered by the Agency for Health Care Administration. A clinical laboratory is the physical location where statutorily defined services "are performed to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition."[14] Health care facilities (including physician offices) performing any clinical laboratory testing are required to obtain a state clinical laboratory license and a federal Clinical Laboratory Improvement Amendment (CLIA) certificate.[15]

Current Florida law permits clinical laboratories to examine human specimens only at the request of a "licensed practitioner or other person authorized by law[16] to use the findings of clinical laboratory examinations."[17] Human specimens may include, but are not limited to, blood, tissue, or urine. A "licensed practitioner" is a Florida-licensed medical physician, physician assistant, osteopathic physician, chiropractic physician, podiatric physician, dentist, naturopathic physician, or advanced registered nurse practitioner.[18] The statute also recognizes practitioners from another state licensed under similar statutes, with certain qualifiers, as a licensed practitioner for purposes of chapter 483, F.S. Florida law requires clinical laboratories to accept human specimens from these licensed practitioners, with the exception of advanced registered nurse practitioners, if the specimen and test are the type performed by the clinical laboratory. Clinical laboratories may refuse to accept a specimen from one of these practitioners only if there is a history of nonpayment for services by the practitioner. Additionally, a clinical laboratory may not charge a different price for tests based on the type of licensed practitioner submitting the test.[19]

As a result, Florida law permits a clinical laboratory to examine human specimens at the request of an ARNP, but it does not require the laboratory to do so. According to the Department of Health, ARNPs commonly submit specimens under the name of another practitioner, from whom clinical laboratories are required to accept specimens. Florida law requires clinical laboratories to report test results directly to the person who requested it.[20]

Effect of Proposed Changes

The bill amends s. 440.102, F.S., Workers' Compensation, to repeal the requirement that a licensed or certified clinical laboratory perform an initial drug test for an employee or job applicant in a drug-free workplace. As a result, an initial drug test may be conducted at the employer's work site.

The bill also amends s. 483.181, F.S., Health Testing Services, to include Florida-licensed ARNPs in the list of practitioners from whom clinical laboratories must accept specimens submitted for examination. In doing so, the bill applies the same conditions regarding a clinical laboratory's right to not accept specimens from a specified health care provider based on nonpayment history and the prohibition that a clinical laboratory cannot charge different prices to different health care practitioners for the same service.

The bill is effective July 1, 2009.

B. SECTION DIRECTORY:

Section 1. Amends s. 440.102, F.S., relating to drug-free workplace program requirements.

Section 2. Amends s. 483.181, F.S., relating to the acceptance, collection, identification, and examination of specimens.

[14] Section 483.041(2), F.S.
[15] Section 483.101, F.S.; Agency for Health Care Administration, "Clinical Laboratories," http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/clinical.shtml (last visited February 13, 2009).
[16] "Other persons authorized by law" include individuals submitting a sample of his or her own blood, if the sample was taken using a home HIV test kit approved by the U.S. Food and Drug Administration. Section 483.181(1), F.S.
[17] Section 483.181(1), F.S.
[18] Section 483.041(7), F.S.
[19] Section 483.181(5), F.S.
[20] Section 483.181(2), F.S.

Section 3. Provides an effective date of July 1, 2009.

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.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax sharing with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The department appears to have sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the changes to s. 483.181, F.S., may have a positive impact to public health. The ARNP practice of submitting specimens under the name of another practitioner may contribute to delays in the initiation of treatment for infections when the results are returned not to the practitioner who collected the specimen and who manages the patient, but rather, to the professional colleague who submitted the specimen. Requiring clinical laboratories to accept specimens from ARNPs will allow them to return the results directly to the ARNP.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 18, 2009, the Health and Family Services Policy Council adopted an amendment that repeals the requirement that a licensed or certified clinical laboratory perform an initial drug test for an employee or job applicant in a drug-free workplace.

The bill was reported favorably with a council substitute. The analysis is drafted to reflect the council substitute.