

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 695 Clinical Laboratories

SPONSOR(S): Garcia and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 716

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|------------------------------|------------------|-------------|----------------|
| 1) <u>Healthcare Council</u> | <u>15 Y, 0 N</u> | <u>Owen</u> | <u>Gormley</u> |
| 2) _____ | _____ | _____ | _____ |
| 3) _____ | _____ | _____ | _____ |
| 4) _____ | _____ | _____ | _____ |
| 5) _____ | _____ | _____ | _____ |

SUMMARY ANALYSIS

The bill requires clinical laboratories to accept human specimens submitted for examination by Florida-licensed advanced registered nurse practitioners.

The bill appears to have no fiscal impact on the state or local government.

The bill is effective July 1, 2008.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

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

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Nursing

Part I of chapter 464, F.S., regulates the profession of nursing. The part provides definitions and requirements for nursing licensure of licensed practical nurses, registered nurses, and advanced registered nurse practitioners. 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 advanced nurse practitioner (ARNP) is defined as “any person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice.”¹ An ARNP must have a master’s degree and can be a certified nurse anesthetist, certified nurse midwife, or nurse practitioner.² 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 postbasic 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.
- Graduation from a program leading to a master’s degree in a nursing clinical specialty area with preparation in specialized practitioner skills.³

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.⁴

Under the Nurse Practice Act, an ARNP must perform his or her authorized functions under an established protocol that must be filed with the Board of Nursing.⁵ Practitioners licensed in the medical practice, osteopathy, or dentistry must supervise the ARNP within the framework of the protocol.⁶ The Board of Nursing and the Board of Medicine have filed identical administrative rules⁷ setting forth standards for the protocols, which establish obligations on medical physicians, osteopathic physicians, and dentists who enter into protocol relationships with ARNPs. 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:

¹ Section 464.003(7), F.S.

² According to s. 464.012(1)(c), F.S., applicants applying to become an ARNP graduating on or after October 1, 1998, must have a master’s degree for certification. Additionally, applicants who want to be a registered nurse anesthetist and graduate on or after October 1, 2001, must have a master’s degree.

³ Section 464.012(1), F.S.

⁴ Florida Board of Nursing, Florida Department of Health, “Frequently Asked Questions,” http://www.doh.state.fl.us/mqa/nursing/nur_faq.html (follow “ARNP” link) (last visited April 3, 2008).

⁵ Section 464.012(3), F.S.

⁶ *Id.*

⁷ 64B9-4.010 and 64B8-35.002, F.A.C.

- 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;
- Performing acts of medical diagnosis and treatment, prescription, and operation.⁸

An ARNP may also perform certain duties within his or her specialty.⁹ Although ARNPs may prescribe medications in accordance with the protocol and under the authority of the supervising physician, they cannot prescribe controlled substances.

Clinical Laboratories

Clinical laboratories are governed by the provisions of part I, chapter 483, F.S. 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.”¹⁰ The state of Florida requires any facility that operates as a clinical laboratory to obtain a state clinical laboratory license as well as a federal Clinical Laboratory Improvement Amendment certificate.¹¹

Under Florida law, a “clinical laboratory may examine human specimens at the request only of a licensed practitioner or other person authorized by law to use the findings of clinical laboratory examinations.”¹² A “licensed practitioner” is defined under the regulation for clinical laboratories to mean a Florida-licensed medical physician, physician assistant, osteopathic physician, chiropractic physician, podiatric physician, dentist, naturopathic physician, or advanced registered nurse practitioner.¹³ 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.

Section 483.181, F.S., permits a clinical laboratory to examine human specimens at the request of an ARNP, but it does not require the laboratory to do so. However, a clinical laboratory *must* accept a human specimen for examination by a Florida-licensed medical physician, physician assistant, osteopathic physician, chiropractic physician, naturopathic physician, or dentist, if the specimen and test are the type performed by the clinical laboratory. The only way a clinical laboratory may refuse a specimen from these practitioners is based upon a history of nonpayment for services by the practitioner. Additionally, a clinical laboratory may not charge a different price for tests based on what kind of licensed practitioner is submitting the test.¹⁴

Effect of Proposed Changes

The bill amends s. 483.181, F.S., to require clinical laboratories to accept specimens submitted for examination by Florida-licensed ARNPs. The clinical laboratory could only refuse a specimen submitted by an ARNP based on a history of nonpayment. Additionally, a clinical laboratory could not charge prices to an ARNP that are different from the prices the laboratory charges other licensed practitioners.

The bill is effective July 1, 2008.

⁸ Sections 464.012(3) and 464.003(d), F.S.

⁹ Section 464.012(4), F.S.

¹⁰ Section 483.041(2), F.S.

¹¹ Agency for Health Care Administration, “Clinical Laboratories,”

http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Laboratory_Licensure/clinical.shtml (last visited April 3, 2008).

¹² Section 483.181(1), F.S.

¹³ Section 483.041(7), F.S.

¹⁴ Section 483.181(5), F.S.

C. SECTION DIRECTORY:

Section 1: Amends s. 483.181, F.S., regarding the acceptance, collection, identification, and examination of specimens.

Section 2: Provides an effective date of July 1, 2008.

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:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

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:

None.

D. STATEMENT OF THE SPONSOR

None submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES