Health Care Regulation Committee

Wednesday, March 8, 2006
10:00 AM - 12:00 PM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

House of Representatives

Committee on Health Care Regulation

AGENDA

March 8, 2006
10:00 AM - 12:00 PM
212 Knott Building

I. Opening Remarks by Chair Garcia

II. Consideration of the following bills:

HB 427 – Surgical First Assistance by Rep. Homan

HB 675 – Sale or Lease of a County, District, or Municipal Hospital by Rep. Pickens

HB 699 – Health Care by Rep. Negron

HB 747 – Health Professionals Treating Speech or Hearing Disorders by Rep. Greenstein

HB 903 – Pharmacy Common Databases by Rep. Traviesa

III. Closing Remarks

IV. Adjournment

210 House Office Building, 402 South Monroe Street, Tallahassee, Florida 32399-1300 (850) 487-3771

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 427 Surgical First Assistance
SPONSOR(S): Homan and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1044

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Insurance Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 427 establishes the licensure of certified surgical first assistants. A surgical assistant works under the direct supervision of a surgeon and provides technical functions that help a surgeon perform an operation. The bill creates a regulatory scheme, provides definitions, scope of practice, employment guidelines, continuing education, accountability, and rules and guidelines. The licensure is voluntary. Section 11.62, F.S., the Sunrise Act that establishes criteria for new regulation of professions, states that it is the intent of the Legislature that no profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage; and no profession or occupation be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation. The Sunrise Act requires proponents of regulation to provide information to the Legislature that establishes the need and effects of regulation. The proponent for the regulation that submitted this information is the Florida Association of Surgical Assistants (FASA). The bill provides for regulation of approximately 432 certified practitioners, which currently perform the duties of a surgical first assistant.

According to the Department of Health, hospitals are largely responsible for providing oversight and setting standards for the performance of surgical assistants in Florida. Proponents for licensure of certified surgical first assistants have not provided sufficient documentation, based on the evaluation criteria established in s. 11.62, F.S., to warrant the establishment of a new profession at this time. They stated, "we know of no documented harm to the public" and "no instances of consumer injury were found."

Currently, surgeons have been unable to bill for the services of a surgical assistant unless the assistant was licensed as a physician assistant or nurse. The bill amends s. 627.419(6), F.S., Part II of the Florida Insurance Code, to allow for direct reimbursement of a certified first assistant.

Fiscal Impact: Currently, these services are covered by global payments made by health insurance plans to hospitals and surgeons. Any increased payments required by this bill will have the effect of increasing the cost of health care. According to the Department of Health, this profession is expected to operate in a deficit and the allocated expenses for administrative, complaint, investigative, and prosecution services range from $19,000 and $243,000 or more annually in addition to the direct expenses for licensure.

The bill will take effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government-The bill increases regulation of hospital surgical practices and provides for the creation of a regulatory scheme for a new profession.

B. EFFECT OF PROPOSED CHANGES:

HB 427 provides for the regulation of certified surgical first assistants. A surgical assistant works under the direct supervision of a surgeon and provides aid in operative technical functions that help a surgeon perform a safe operation. A wide range of health professionals function as surgical assistants, such as physician assistants, nurses, and surgical technologists.

The bill does not establish mandatory licensure. The bill provides that a certified surgical first assistant license is not required of a registered nurse, an advanced registered nurse practitioner, a registered nurse first assistant, or a physician assistant as a condition of employment. The bill creates a regulatory scheme, provides definitions, scope of practice, employment guidelines, continuing education, accountability, rules and guidelines and proposes licensure. According to the proponents, the bill creates a system of monitoring to safeguard the consumer. The bill provides for regulation of an estimated 432 certified practitioners, who currently perform the duties of a surgical first assistant.

The bill provides for the regulation of a new profession, certified surgical first assistants. According to s. 11.62, F.S., the Sunrise Act, it is the intent of the Legislature that:

- No profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose; and

- No profession or occupation be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

In determining whether to regulate a profession or occupation, s. 11.62, F.S., requires the Legislature to consider the following:

I. Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
II. Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
III. Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
IV. Whether the public is or can be effectively protected by other means; and
V. Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

Section 11.62, F.S., requires the proponents of regulation to submit information, which is structured as a sunrise questionnaire to document that regulation meets these criteria. The effects section of the bill analysis is structured to address these five criteria. A sunrise questionnaire was submitted to staff by the proponents of the legislation to assist the Legislature in determining the need for regulation of

certified surgical first assistants and analyzing the proposed legislation seeking to establish regulation under the Department of Health. The proponent for the regulation and entity responsible for submitting the sunrise questionnaire is the Florida Association of Surgical Assistants (FASA). FASA represents the certified surgical first assistants and during their 2005 annual business meeting, the Board of Directors responded to the requests of its members by selecting a core group of nine practitioners to represent them in this endeavor.

CRITERIA FOR THE PROPOSED PROFESSIONAL REGULATION

I. Substantial Harm or Endangerment

According to the information provided to staff in response to the sunrise questionnaire, there is an external and internal need for a regulatory standard for these reasons:

- There is an inherent risk of physical harm in surgery and a wide range of health care professionals, with varying educational and professional experience who perform as a surgical first assistant.
- The lack of a standard of practice places an undue burden and responsibility on hospitals to determine whether or not a practitioner will be allowed to practice in a given hospital.
- The lack of a regulatory body to ensure that only the most qualified individuals are involved in the practice of surgical first assisting, places a great risk on the general public.
- The lack of any recordkeeping by a centralized regulatory agency endangers the public health in as much as there is no way for a patient to ensure that the particular individual performing as a surgical first assistant is qualified to assist in surgery and that they do not have a history of malpractice in the profession.
- There is a demand from certified surgical assistants to ensure that only qualified individuals are allowed to practice.

However, based on the response provided by the proponents of this legislation, "*we know of no documented harm to the public*" and "*no instances of consumer injury were found.*" The proponents for regulation were not able to provide estimated numbers of complaints against professionals practicing in this profession. The bill does not require licensure and does not provide any new protections for patient safety, therefore does not meet the safety criteria for licensure.

II. Specialized Skill or Training, and Measurability

According to the information provided in the sunrise questionnaire, the practice of the profession requires specialized training and may require practitioners to handle or operate electrosurgical instruments, endoscopic or laproscopic instrumentation, laser equipment or gas beam coagulation equipment as well as other technology. Surgical assistants are required to use sophisticated equipment as well as other technology, which require highly specialized knowledge and skill that is acquired through education and experience.

Proponents of the legislation claim that surgeons depend on certified surgical first assistants to perform skills, offer input and insight based on his/her knowledge of a procedure or equipment used, for the task at hand. The proponents also state "there is no consensus of competency in Florida, and that is why the bill proposes to create guidelines through licensure." According to the questionnaire, "competent practice can be measured and currently the surgeons and the credentialing body at the hospital perform practitioner peer review. The burden is placed on the hospital and the employer to grade competency."

Surgical first assistants work under the direct supervision of the surgeon and may be asked to assist in a wide variety of devices in many multi-specialties. The surgeon is always present, but according to the proponents of the legislation, the judgment and the skill of the assistant plays a large part in the success of a surgery.

However, based on a study conducted by the Government Accountability Office (GAO)[1], "*there is no widely accepted set of uniform requirements for experience and education* that the health professionals who serve as assistants-at-surgery [or surgical assistants] are required to meet." "GAO found that there was insufficient information about the quality of care provided by assistants-at-surgery [or surgical assistants] generally, or by a specific type of health professional, to access the adequacy of the requirements for members of a particular profession to perform the role." According to the questionnaire, currently, first assistants must provide documented experience and submit to a written test that serves to document the knowledge, skills and abilities they possess. Each of the national credentialing agencies sets their own criteria requirements and examination.

It is not clear that only one licensed profession should perform the duties of a certified surgical first assistant. The educational requirements required of a surgical assistant seeking certification by any of the three accreditation credentialing bodies identified in the bill are varied.

III. Unreasonable Effect on Job Creation or Job Retention

According to the sunrise questionnaire, "hospitals set their own policy and procedures regarding who can perform as a surgical assistant. Certified Surgical Technologists, non-certified surgical technologists, along with other non-certified assistive personnel, may be employed by hospitals and out-patient surgery centers throughout the state. It would be impossible to estimate how many individuals this encompasses. Best estimate would be over 1700."

The proponents of the regulation state that registered nurse first assistants and physician assistants provide the same service in the operating room as a certified surgical first assistant, but have a larger scope of practice that may involve the assessment of the patient before and after surgery. Certified surgical first assistants are trained specifically to assist the surgeon in the operating room.

Since the bill does not require licensure, there may not be an unreasonable effect on job creation or retention.

IV. Can the Public be Effectively Protected by Other Means?

The proponents for the regulation claim that the existing protections available to consumers are insufficient, and that the burden of protecting the public lies on hospitals and professional organizations. They contend that there are other means to protect the public, but they are not being utilized to oversee the duties of surgical first assistants. These other means are: code of ethics; codes of practice enforced by professional associations; dispute-resolution mechanisms such as mediation or arbitration; recourse to current applicable law; regulation of those who employ or supervise practitioners; caveat empor, i.e., "let the buyer be beware"; and supervision that is the burden of the employer and/or facility. Proponent's state that volunteer certification as it currently exists, is good, but does not offer all the safety nets that government intervention provides in the form of licensure.

It appears that the alternatives to professional licensure, currently utilized, are effective. Because hospitals currently oversee safety in surgery and surgeons are responsible for the practice of their surgical assistants, and no instances of harm have been documented.

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[1] United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.

V. Favorable Cost-effectiveness and Economic Impact

According to the sunrise questionnaire, approximately half a million people undergo surgery annually in Florida. "The regulation of this profession will not affect this estimate." Proponents estimate that the cost to insurance companies will increase, but that policyholders have already paid for the services. Insurance companies will be expected to pay for provided services, such as, the services provided by a surgical first assistant. The proponents of the bill project that half of the estimated 432 certified professionals will seek licensure in Florida and another 100-150 applicants will apply annually.

The bill provides for the regulation of the profession by an existing board, requires credentialing and licensure, licensure renewal, enforcement for noncompliance to regulatory guidelines.

See the "Fiscal Impact on State Government" for the Department of Health's projections on the fiscal impact.

BACKGROUND INFORMATION

Legislative History

The occupational group seeking regulation is the Certified Surgical First Assistants. To date, there is no history of regulation or attempts at regulating this profession in Florida.

Who is a Certified Surgical First Assistant?

A wide range of health professionals function as surgical assistants. Surgical assistants may be referred to as first assistants or assistants-at-surgery. Examples of such health professionals that function as surgical assistants are:

- Physicians (post-residency)
- Physicians in residency
- Registered nurses, including those in surgical specialties, such as orthopedics
- Licensed practical nurses
- Nurse practitioners
- Clinical nurse specialists
- Certified registered nurse assistants
- Surgical technologists
- Physician Assistants
- Ophthalmic assistant/technicians
- Surgical assistants
- Orthopedic technologists
- Orthopedic physician assistants
- International medical graduates

Profile of the Profession

According to information provided in the sunrise questionnaire, the American College of Surgeons defines "*surgical assistants*" as those who provide aid in exposure, hemostasis, closure and other operative technical functions that help the surgeon carry out a safe operation with optimal results. Some of the specific tasks include: making initial incisions (opening), exposing the surgical site (retracting), stemming blood flow (hemostasis), reconnecting tissue (suturing) and completing the operation be reconnecting external tissue (closing). Additionally, surgical assistants should possess knowledge of sterility requirements, aseptic techniques, draping procedures, operating room equipment, drain placement and cauterization, and dressing techniques.

Scope of Practice as Defined in the Bill

The bill provides a scope of practice for a certified surgical first assistant which is limited to surgical assisting and tasks that are delegated by the supervising physician. A definition of "surgical assisting" is provided that means providing aid under the direct supervision in exposure, hemostasis, closures, and other intraoperative technical functions that assist a physician in performing a safe operation with optimal results for the patient. The bill also provides that the duties of a certified surgical first assistant are limited to the scope of the certification in surgical assisting functions while under the direct supervision of a physician. However, the bill does not provide a definition or explanation for the "scope of certification." The bill stipulates that a certified surgical first assistant may only work in a medical clinic, hospital, ambulatory surgical center, or similar medical institution.

The bill specifies that the physician supervising a certified surgical first assistant shall be qualified in the medical areas in which the certified assistant is to perform and may be responsible and liable for the performance and acts and omissions of the assistant.

Certification Bodies and the Requirements for Certification

Currently there is a wide range of non-physician allied health professionals trained as surgical assistants or technologists in a variety of programs. According to the Department of Labor, most employers prefer to hire surgical assistants or technologists who are certified. Surgical assistants or technologists may obtain voluntary professional certification by graduating from an accredited program and passing a national certification examination. To qualify to take the exam, candidates follow one of three paths: complete an accredited training program, undergo a 2-year hospital on-the-job training program, or acquire seven years of experience working in the field.

The bill requires certified surgical first assistants to be certified by one of the following three professional organizations:

- The American Board of Surgical Assistants (ABSA), founded in 1987, administers a national certification examination for surgical assistants. This body provides for surgical assistant-certified or (SA-C) certification title. Their examination covers all surgical disciplines and areas of preoperative medicine. It evaluates knowledge of surgical anatomy, procedures and techniques, diagnostic studies, emergencies, OSHA regulations and general patient safety.

- The National Surgical Assistant Association (NSAA), which began in Virginia in 1979. This body provides for certified surgical assistant (CSA) certification title. The National Surgical Assistant Association established practice standards and develop a certification examination with the help of the Department of Surgery at Norfolk General Hospital.

- The Liaison Council on Certification for the Surgical Technologist (LCC-ST), was established in 1974 as the certifying agency for surgical technologists. This body provides for certified first assistant (CFA) certification title. The Council determines the eligibility for the granting and revocation of certification of surgical technologists and first assistants.

Current Statutory Prohibition for Unlicensed Activity in Surgery unless Authorized and Pass a Competency Assessment

Section 395.0197(1)(b) 3., F.S., prohibits unlicensed persons from assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment. Assistance or participation must be done under the direct and immediate supervision of a licensed physician and must not be an activity that may only be performed by a licensed health care practitioner.

Education and Regulation in Other States

According to a study conducted by the U.S. General Accounting Office (GAO), [2] there is no widely accepted set of uniform requirements for experience and education that the health professionals who serve as assistance-at-surgery or surgical first assistants are required to meet. The health professionals whose members provide assistants-at-surgery services have varying educational requirements. No state licenses all the health professionals who serve as assistants-at-surgery, and the health professional licenses that states do issue typically attest to the completion of broad-based health care education, rather than education or experience as an assistant. Furthermore, the certification programs developed by the various non-physician health professional groups whose members assist at surgery differ. The GAO found that there was insufficient information about the quality of care provided by assistants-at-surgery generally, or by a specific type of health professional, to assess the adequacy of the requirements for members of a particular profession to perform the role.

Based on the findings in the GAO study, in January 2004 only one state, Texas, had a specific assistant-at-surgery license. Even though Texas licenses assistants-at-surgery, a license is not required to serve as an assistant-at-surgery. According to the proponents of the bill two additional states now regulate surgical first assistants: Kentucky and Illinois.

Surgical Education, Experience Requirements, and Licensure Requirements for Surgical First Assistants

Health Profession	General Education Requirements	Licensure Requirements in All States	Example of Surgical Experience Requirements
Physician			
Physicians (post-residency)	Doctor of medicine or osteopathy	Yes	
Physician in residency	Doctor of medicine or osteopathy	Yes	
Nurse			
Registered nurse, including surgical specialties * (*A variety of surgery-related certifications are available for nurses. Some of these are for surgical specialties. Orthopedic nurse certified requires 1,000 hours of experience as an orthopedic nurse. Certified plastic surgical nursing requires 2 years experience in plastic surgery. Both certifications include operating room experience, but neither requires OR experience.)	Associate's or bachelor's degree in nursing or non-degree hospital diploma	Yes	Requirements vary by certification program, but surgical experience is not required for certain surgical-related certifications
Nurse practitioner	Master's of science in nursing or non-degree certificate	Yes	
Clinical nurse specialist	Master's of science in nursing	Yes	
Certified registered nurse first assistant	Bachelor's degree and certification program with 2-3 surgical classes	Yes	2,400 hours of operating room experience in the scrub or circulating role and 2,000 hours as assistant-at-surgery
Licensed practical nurse	1-year program	Yes	

[2] United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.

Other health professions			
Surgical technologist	Associate's degree, military or non-degree certificate	No	2 years of surgical experience
Physician assistant	Associate's or bachelor's degree or non-degree certificate	Yes	
Ophthalmic assistant/technician	Certificate programs or work experience	No	18 months of surgical experience
Surgical assistant	Bachelor's degree or non-degree certificate	No	2-3 years of surgical assistant experience, depending upon certification program
Orthopedic physician assistant	Associate's degree, military or non-degree certificate, or 5 years of experience	No	1 year surgical experience
International medical graduate	Non-U.S. degree in medicine	No	

Source: 2004 GAO Report Medicare Payments for Assistants-at-Surgery

Medicare Reimbursement of Surgical Assistants

A goal of Medicare is to ensure that payments to providers are for the appropriate amount and only for medically necessary services.[3]

According to the GAO report on Medicare costs,[4] surgical assistants have a wide range of educational training and expertise, and different levels of professional requirements that do not justify the same level of reimbursement by Medicare.

Depending on the procedure performed, and the qualifications and training of the provider assisting in surgery, the services may be separately billable to Medicare. Medicare reimburses only licensed personnel as assistants-at-surgery and does not reimburse for surgical assistants such as registered nurse first assistants, orthopedic physician assistants, licensed practical nurses, certified surgical technologists, or other licensed or non-licensed personnel. The hospital or surgeon typically pays these practitioners.

When Medicare reimburses for an assistant-at-surgery, the reimbursement rate is not at the full level received by a physician. The reimbursement rate depends on the level of education and training of the assistant. Physicians are paid 16 percent of the physician fee for surgery; physician assistants, clinical nurse specialists and nurse practitioners are paid 85 percent of 16 percent (or 13.6 percent) of the physician fee.

Impact of the Bill on New Insurance Policies and Current Statutory Provisions for Reimbursement

The bill amends s. 627.419(6), F.S., Part II of the Florida Insurance Code relating to the construction of insurance policies, requiring that, if a policy pays for services provided by surgical first assisting benefits, then the policy is construed to make payments to certified surgical first assistants or their employers. The bill applies to individual and group health insurance policies, except for small group basic and standard policies. The bill does not require an insurer to directly reimburse a certified first assistant if the assistant is paid or will be paid for their services by a health care facility. Currently, these services are covered by global payments made by health insurance plans to hospitals and surgeons. Any increased payments required by this bill will have the effect of increasing the cost of

[3] United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.

[4] United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.

health care. According to the Office of Insurance Regulation, the bill does not apply to health maintenance organizations contracts.

Currently, s. 627.419(6), F.S., requires health insurance policies, plans and contracts that pay for surgical first assisting to reimburse registered nurse first assistants or their employers and employers of physician assistants for assistance in surgery. Reimbursement is required only if an assisting physician, licensed under chapters 458 or 459, F.S., would be covered, and the physician assistant or registered nurse first assistant performs such services as a substitute for the physician.

According to the Office of Insurance Regulation, the bill does not address polices renewed after the effective date. Therefore, the bill will apply prospectively to new policies issued after the effective date. It was unclear to the Office of Insurance Regulation, if this new, direct payment requirement will significantly impact claims, payments for services provided by certified surgical assistants which may be currently covered under the general reimbursement for a covered surgical procedure.

Even though the Office of Insurance Regulation states that the bill's provisions do not apply to health maintenance organization (HMO) contracts, the language of the bill states that "when any health insurance policy, health services plan or other contract provides for payment for surgical first assisting benefits or services..." If HMOs' contracts provide those services then arguably they would have to comply with the provisions of this bill.

C. SECTION DIRECTORY:

Section 1. Creates s. 458.3465, F.S., to provide definitions, performance requirements, duties and scope of practice, employment guidelines, licensure requirements, application fees and renewal fees, authority to impose penalties, specification for licensure status, title protection, rule making authority, fee guidelines, and states that supervising physicians are liable for certain actions or omissions of a certified surgical first assistant.
Section 2. Amends s. 627.419, F.S., to provide payment mechanisms for physician assistants providing surgical first assistant services, and places payment provisions for certified surgical first assistants.
Section 3. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

The following the fiscal impact was provided by the Department of Health.

1. Revenues:

Estimated Revenue	1st Year	2nd Year
$100 initial application fee	$50,000	$5,000
$200 initial licensure fee	$100,000	$10,000
$5 unlicensed activity fee	$2,500	$250
Total Estimated Revenue	$152,500	$15,250

This bill provides that the boards, not the department, will set the fees. Assuming that the boards impose the same fees as currently provided for Anesthesiologist Assistants and Physician Assistants, the estimated revenues were based on 500 applicants in year 1 and 50 applicants in year 2. Revenues were computed based on a $100 initial application fee; a $200 initial licensure fee, and a $5 unlicensed activity fee. The bill states that the application fee may not exceed $750 and a renewal fee no more than $1,000.

2. Expenditures:

Estimated Expenditures	1st Year	2nd Year (Annualized/Recurr.)
Salaries		
.5 FTE, PG 15 –Licensure (BOM)	$17,586	$17,586
.5 FTE, PG 15 – Licensure Maint (BOM)	$17,586	$17,586
.5 FTE, PG 13 – Comm Svcs (BMS)	$12,156	$16,207
.5 FTE, PG 13 – Client Svcs (BMS)	$12,156	$16,207
.5 FTE, Sr Attorney, PG 230 (PSU)	$26,725	$35,633
1 FTE, PG 15 (PSU)	$26,379	$35,172
Expense		
Non-recurring for 5 positions	$13,955	
Recurring exp for 5 positions	$25,975	$25,975
Non-recurring exp for 1 position	$3,343	
Recurring exp w/max travel 1 position	$15,757	$15,757
Processing initial and renewal applications	$5,138	$5,138
Operating Capital Outlay		
Non-recurring for 5 positions	$10,500	
Non-recurring for 1 position	$1,900	
Human Resource Services		
6 positions	$2,358	$2,358
Total Estimated Expenditures	$191,514	$187,619

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This may increase the cost of health care as surgeons may be able to bill for services not previously billable. Regulation of health care providers may have a positive impact on patient safety. This bill encourages all surgical assistants to get certified or face smaller employment opportunities.

D. FISCAL COMMENTS:

Boards of licensed professions with a small licensee base often operate in a deficit. Based on the number of estimated licensees, this profession is expected to operate in a deficit depending on the amount of the renewal fee, and will require subsidization from professions operating with a surplus cash balance. Expenses for administrative, complaint, investigative, and prosecution services are allocated to each board by DOH, based upon the level of services provided to that board. Allocated expenses for certified surgical first assistants could range between $19,000 and $243,000 or more annually (depending on the enforcement activity) in addition to the direct expenses shown in this analysis.

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 an 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 revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health with adequate rule-making authority to implement the provisions provided for in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Proponents for licensure of certified surgical first assistants have not provided sufficient documentation, based on the evaluation criteria established in s. 11.62, F.S., to warrant the establishment of a new profession at this time.

According to the Department of Health, the bill is similar to the regulation of Anesthesiologist Assistants; however, the following issues should be considered:

- The bill requires that applicants have certification from one of three national organizations; however, one of these organizations, The American Board of Surgical Assistants, does not require graduation from a program approved by the Commission on Accreditation of Allied Health Education Programs. As a result, the State of Kentucky will no longer accept certification from this organization for their surgical assistant certification program.

- The bill provides that the Board issues licenses and the department renews licenses. This is a typographical error and can be easily addressed.

- The bill provides that the employment arrangement of a certified surgical first assistant cannot be limited in any way by statute or rule of the board. It is unclear how this would affect the ability of the board to ensure compliance of the certified surgical first assistants and the supervising physicians with statutes and rules and to take disciplinary actions for violations thereof.

- The bill provides for reciprocity which will limit the ability of the Board to ensure that all licenses meet the same requirements for certification as a certified surgical first assistant. With licensure in one state, they could be licensed here without meeting the Florida education and licensure standards.

- The bill limits certified surgical first assistants to a "medical clinic, hospital, ambulatory surgical center, or similar medical institution." It is unclear where the certified surgical first assistant would not be able to practice.

The Board of Medicine has requested clarification of three issues: reciprocity, whether the profession would operate in a deficit, and the language of the bill which has the board issuing licenses.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to surgical first assistance; creating s.
3 458.3465, F.S.; providing definitions; providing
4 requirements for the performance of supervising
5 physicians; providing the duties and scope and location of
6 practice for certified surgical first assistants;
7 providing contracting and employment guidelines for
8 physicians, hospitals, clinics, or ambulatory surgical
9 centers employing certified surgical first assistants;
10 providing licensure criteria for certified surgical first
11 assistants; providing for application fees and licensure
12 renewal fees; providing for licensure renewal; providing
13 continuing education requirements; authorizing the Board
14 of Medicine to impose penalties; providing scope of a
15 certified surgical first assistant's license; providing
16 for reciprocity of licenses among states; providing for
17 inactive and delinquent status; providing that an
18 unlicensed person who holds himself or herself out as, or
19 indicates or implies that he or she is, licensed commits a
20 third degree felony and is subject to applicable
21 penalties; providing for denial, suspension, or revocation
22 of licensure; authorizing the board to adopt rules;
23 providing that supervising physicians may be liable for
24 certain acts or omissions of certified surgical first
25 assistants; providing guidelines for the use of fees
26 collected by the board; amending s. 627.419, F.S.;
27 providing for payments to a physician assistant under
28 contracts providing for payment for surgical first

29 assisting benefits or services; including certified
30 surgical first assistants, as defined, within certain
31 benefits or services payment provisions; limiting
32 application; providing an effective date.
33
34 Be It Enacted by the Legislature of the State of Florida:
35
36 Section 1. Section 458.3465, Florida Statutes, is created
37 to read:
38 458.3465 Certified surgical first assistants.--
39 (1) DEFINITIONS.--As used in this section:
40 (a) "Board" means the Board of Medicine.
41 (b) "Certified surgical first assistant" means a person
42 who provides primary surgical assistance to the primary surgeon
43 during a surgical procedure, is listed on the operative record
44 as the first assistant, and meets the qualifications for
45 licensure under this section.
46 (c) "Continuing medical education" means courses
47 recognized and approved by the board, the Liaison Council on
48 Certification for the Surgical Technologist, the National
49 Surgical Assistant Association, the American Board of Surgical
50 Assistants, the American Medical Association, the American
51 Osteopathic Association, or the Accreditation Council on
52 Continuing Medical Education.
53 (d) "Direct supervision" means supervision by a delegating
54 physician who is physically present and who personally directs
55 delegated acts and remains immediately available to personally
56 respond to any emergency until the patient is released from the

57 operating room or the physician's care and has been transferred
58 to the care and responsibility of another physician.
59 (e) "Surgical assisting" means providing aid under direct
60 supervision in exposure, hemostasis, closures, and other
61 intraoperative technical functions that assist a physician in
62 performing a safe operation with optimal results for the
63 patient.
64 (2) PERFORMANCE OF SUPERVISING PHYSICIAN.--Each physician
65 or group of physicians supervising a certified surgical first
66 assistant shall be qualified in the medical areas in which the
67 certified surgical first assistant is to perform and may be
68 individually or collectively responsible and liable for the
69 performance and the acts and omissions of the certified surgical
70 first assistant.
71 (3) PERFORMANCE OF CERTIFIED SURGICAL FIRST ASSISTANTS.--
72 (a) A certified surgical first assistant may perform
73 duties limited to the scope of certification in surgical
74 assisting functions while under the direct supervision of a
75 physician.
76 (b) The scope of practice of a certified surgical first
77 assistant is limited to surgical assisting and tasks delegated
78 by the supervising physician.
79 (c) A certified surgical first assistant may only perform
80 his or her duties in a medical clinic, hospital, ambulatory
81 surgical center, or similar medical institution.
82 (4) EMPLOYMENT OF CERTIFIED SURGICAL FIRST ASSISTANTS.--
83 (a) A physician or hospital is not required to contract
84 with a certified surgical first assistant.

85 (b) A health maintenance organization, preferred provider
86 organization, or health benefit plan shall not require a
87 physician, hospital, clinic, or ambulatory surgery center to
88 contract with a certified surgical first assistant as a
89 condition of payment to a certified surgical first assistant.
90 (c) The employment arrangement of a certified surgical
91 first assistant shall not be limited in any way by rule of the
92 board or by statute.
93 (5) CERTIFIED SURGICAL FIRST ASSISTANT LICENSURE.--
94 (a) A person desiring to be licensed as a certified
95 surgical first assistant shall apply to the board. The board
96 shall issue a license to any person determined by the board as
97 having met the following requirements:
98 1. Is at least 18 years of age.
99 2. Holds and maintains certification from one of the
100 following recognized certifying agencies:
101 a. The Liaison Council on Certification for the Surgical
102 Technologist.
103 b. The National Surgical Assistant Association.
104 c. The American Board of Surgical Assistants.
105 3. Has completed the application form and remitted an
106 application fee not to exceed $750 as set by the board. An
107 application for licensure made by a certified surgical first
108 assistant shall include:
109 a. A certificate from one of the recognized certifying
110 agencies specified in subparagraph 2.
111 b. A sworn statement of any prior felony convictions.

112 c. A sworn statement of any previous revocation or denial
113 of licensure or certification.
114 (b) A license shall be renewed biennially. Each renewal
115 shall include:
116 1. A renewal fee not to exceed $1,000 as set by the board.
117 2. A sworn statement of no felony convictions in the
118 previous 2 years.
119 (c) Each licensed certified surgical first assistant shall
120 biennially complete 40 hours of continuing medical education or
121 shall hold a current certificate issued by a recognized
122 certifying agency listed in subparagraph (a)2.
123 (d) The board may impose any of the penalties authorized
124 under ss. 456.072 and 458.331(2) upon a certified surgical first
125 assistant if the certified surgical first assistant or the
126 supervising physician has been found guilty of or is being
127 investigated for any act that constitutes a violation of this
128 chapter or chapter 456.
129 (e) A certified surgical first assistant's license:
130 1. Does not authorize the licensee to engage in the
131 practice of medicine or professional nursing.
132 2. Is not required of a registered nurse, an advanced
133 registered nurse practitioner, a registered nurse first
134 assistant, or a physician assistant as a condition of
135 employment.
136 (6) RECIPROCITY.--The department shall allow reciprocity
137 to certified surgical first assistants who are determined by the
138 board to:

139 (a) Be licensed in other states and who are in good
140 standing with their state of licensure and their certifying
141 agency.
142 (b) Have paid appropriate licensure fees.
143 (c) Have complied with all other requirements of the
144 board.
145 (7) INACTIVE AND DELINQUENT STATUS.--A license on inactive
146 or delinquent status may be reactivated only as provided in s.
147 456.036.
148 (8) PENALTY.--A person who has not been licensed by the
149 board and approved by the department and who holds himself or
150 herself out as a licensed certified surgical first assistant or
151 who uses any other term in indicating or implying that he or she
152 is a licensed certified surgical first assistant commits a
153 felony of the third degree, punishable as provided in s.
154 775.082, s. 775.083, or s. 775.084.
155 (9) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.--The
156 board may deny, suspend, or revoke a certified surgical first
157 assistant license if the board determines that the certified
158 surgical first assistant has violated this chapter.
159 (10) RULES.--The board may adopt rules to administer this
160 section.
161 (11) LIABILITY.--Each supervising physician using a
162 certified surgical first assistant may be liable for acts or
163 omissions of the certified surgical first assistant acting under
164 the physician's supervision and control.
165 (12) FEES.--The fees collected by the board under this
166 section shall be used for the licensure and regulation of

167 certified surgical first assistants in accordance with this
168 section.
169 Section 2. Subsection (6) of section 627.419, Florida
170 Statutes, is amended to read:
171 627.419 Construction of policies.--
172 (6)(a) Notwithstanding any other provision of law, when
173 any health insurance policy, health care services plan, or other
174 contract provides for payment for surgical first assisting
175 benefits or services, the policy, plan, or contract is to be
176 construed as providing for payment to a physician assistant or
177 registered nurse first assistant or employers of a physician
178 assistant or registered nurse first assistant who performs such
179 services that are within the scope of a physician assistant's or
180 a registered nurse first assistant's professional license. ~~The~~
181 ~~provisions of~~ This paragraph applies ~~subsection apply~~ only if
182 reimbursement for an assisting physician, licensed under chapter
183 458 or chapter 459, would be covered and a physician assistant
184 or a registered nurse first assistant who performs such services
185 is used as a substitute.
186 (b)1. Notwithstanding any other provision of law, when any
187 health insurance policy, health care services plan, or other
188 contract provides for payment for surgical first assisting
189 benefits or services, the policy, plan, or contract is to be
190 construed as providing for payment to a certified surgical first
191 assistant or to the employer of a certified surgical first
192 assistant who performs such services that are assigned by the
193 supervising physician or osteopathic physician. This paragraph
194 applies only if reimbursement for an assisting physician,

195 licensed under chapter 458 or chapter 459, would be covered and
196 the certified surgical first assistant who performs such
197 services is used as a substitute. As used in this paragraph, the
198 term "certified surgical first assistant" means a person who is
199 a licensed health care provider who is directly accountable to a
200 physician licensed under chapter 458 or an osteopathic physician
201 licensed under chapter 459 and who is certified by the National
202 Surgical Assistant Association, the Liaison Council on
203 Certification for the Surgical Technologist, or the American
204 Board of Surgical Assistants.
205 2. This paragraph does not require an insurer to directly
206 reimburse a certified surgical first assistant if the certified
207 surgical first assistant is paid or will be paid for a surgical
208 procedure by the health care facility at which the surgical
209 procedure is performed.
210 Section 3. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 675 Sale or Lease of a County, District, or Municipal Hospital
SPONSOR(S): Pickens
TIED BILLS: **IDEN./SIM. BILLS:** SB 1190

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Local Government Council			
3) Governmental Operations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 675 amends s. 155.40, F.S., to clarify legislative intent regarding the status of a public hospital that was purchased by a Florida not-for-profit corporation.

There has been a string of court challenges that relate to the public/private status of the Memorial Hospital (now Florida Hospital Deland) in Volusia County. The courts have ruled that even though Florida Hospital Deland is owned by Adventist, it is subject to the Public Records Act in Article I, s. 24 of the Florida Constitution and the Open Government Sunshine Law, codified in s. 119.07, F.S.

Article I, s. 24 of the Florida Constitution and s. 119.07, F.S., both provide avenues for public records exemptions. In order to qualify for an exemption the statute must provide a public necessity statement and must meet certain public purposes. In order to clarify the legislative intent regarding the sale and lease of public hospitals a public records exemption with rationale statement would strengthen the purpose of the bill.

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill clarifies that public hospitals, which are sold to Florida not-profit-corporations, are not subject to Florida public records laws.

B. EFFECT OF PROPOSED CHANGES:

HB 675 amends s. 155.40, F.S., to clarify legislative intent regarding the status of a public hospital purchased by a not-for-profit corporation.

Section 155.40, F.S., was enacted in 1982 to allow local taxing districts the authority to lease their hospitals to not-for-profit Florida corporations and was amended in 1996 to allow the sale of public hospitals to not-for-profit Florida corporations.

A recent court decision in Volusia County ruled that, even though the West Volusia Hospital Authority (the local taxing district) sold their public hospital to Adventist, the hospital must remain subject to the state public records and meetings laws.

The bill clarifies that the Legislature does not intend for public hospitals that are sold to Florida not-for-profits corporations to be subject to public records laws.

The effective date of the bill is July 1, 2006.

BACKGROUND

Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation and Tanner Andrews

The public/private status of the Memorial Hospital (now Florida Hospital Deland) in Volusia County has been the subject of a string of court challenges. The challenges are summarized in the final summary judgment of Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation and Tanner Andrews. The summary judgment lays out the development of the hospital prior to current litigation, background of prior litigation, development of the hospital currently, and legal conclusions.

Development of the Hospital Prior to Current Litigation

In 1957, the Florida Legislature created the West Volusia Hospital Authority (the "Authority"), as an independent taxing district (Ch. 57-2085, 1, Laws of Florida). The Authority developed and operated the West Volusia Memorial Hospital as a publicly owned hospital. From 1957 until 1994, the Authority levied substantial taxes but the Authority was unable to operate the hospital in a fiscally responsible manner and relied heavily on tax-payers to subsidize the hospital. In 1993 the Authority entered into negotiations with Memorial Health Systems (MHS) to lease and operate West Volusia Memorial Hospital. In the contract between MHS and the Authority, MHS agreed to provide indigent care for the indigent sick in the taxing district, and the Authority agreed to reimburse Hospital Corporation for those services.

Background of Prior Legislation

In 1994, News-Journal filed a complaint in the Circuit Court seeking a declaratory decree that the records of MHS were subject to the Public Records Act and the Sunshine Law. The Circuit Court entered a final judgment in favor of MHS. On appeal, the Fifth District Court of Appeal reversed and held that MHS was subject to the Public Records Act and the Sunshine Law. The court concluded that MHS was "acting on behalf of the Authority (News-Journal Corp. v. Memorial Hospital-West Volusia, Inc., 695 So. 2d 418, Fla. 5th DCA 1997). The Supreme Court of Florida upheld the ultimate decision

that MHS was subject to the Public Records Act and the Sunshine Law (Memorial Hospital-West Volusia, Inc. v. News-Journal Corp., 729 So. 2d 373, 383, Fla 1999).

Development of Hospital Recently

On March 23, 2000, MHS delivered notice to the Authority that it intended to terminate the lease contract as of midnight September 30, 2000. The Authority was not interested in running the hospital again and eventually worked out a sale agreement with Adventist, as authorized in s.155.40, F.S. Under the sale agreement the Authority will continue to pay, now Adventist, for indigent care of Volusia County residents. Under the new ownership the name of the hospital was changed to Florida Hospital Deland.

Legal Conclusions

The summary judgment concluded that the Authority has delegated the performance of its public purpose to the Adventist Corporation which is thus subject to the Public Records Act Article I, section 24(a) of the Florida Constitution and the Sunshine Laws of Florida, s. 119.07, F.S.

Public Records Requirements of Leased Hospitals

Section 395.3036, F.S., provides that records and meetings of corporations that lease public hospitals or other public health care facilities are exempt from public records requests. The records of a private corporation are exempt from s. 119.07(1), F.S., and section 24(a), Article I of the State Constitution. The meetings of the governing board of a private corporation are exempt from s. 286.011, F.S., and section 24(b) providing the financial requirements of s. 155.40(5), F.S., are met. In order to qualify for these exemptions the three of the five following criteria must be met:

- The public lessor that owns the public hospital or other public health care facility was not the incorporator of the private corporation that leases the public hospital or other health care facility;
- The public lessor and the private lessee do not commingle any of their funds in any account maintained by either of them, other than the payment of the rent and administrative fees or the transfer of funds;
- Except as otherwise provided by law, the private lessee is not allowed to participate, except as a member of the public, in the decision making process of the public lessor;
- The lease agreement does not expressly require the lessee to comply with the requirements of ss. 119.07(1) and 286.011, F.S. and
- The public lessor is not entitled to receive any revenues from the lessee, except for rental or administrative fees due under the lease, and the lessor is not responsible for the debts or other obligations of the lessee.

Public Records and Public Meetings Laws

Article I, s. 24(a), Florida Constitution, sets forth the state's public policy regarding access to government records. The section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. Article I, s. 24(b), Florida Constitution, sets forth the state's public policy regarding access to government meetings. The section requires all meetings of the executive branch and local government be open and noticed to the public.

The Legislature may, however, provide by general law for the exemption of records and meetings from the requirements of Article I, s. 24, Florida Constitution. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.

Public policy regarding access to government records and meetings is also addressed in the Florida Statutes. Section 119.07(1), F.S., also guarantees every person a right to inspect, examine, and copy any state, county, or municipal record, and s. 286.011, F.S., requires that all state, county, or municipal

meetings be open and noticed to the public. Furthermore, the Open Government Sunset Review Act of 1995[1] provides that a public records or public meetings exemption may be created or maintained only if it serves an identifiable public purpose, and may be no broader than is necessary to meet one of the following public purposes:

- Allowing the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protecting sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety. However, only the identity of an individual may be exempted under this provision; or,
- Protecting trade or business secrets.

C. SECTION DIRECTORY:

Section 1.- Amends s. 155.40, F.S., to clarify legislative intent regarding the purchase of a hospital.

Section 2.- Provides an effective date of July 1, 2006.

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:

[1] Section 119.15, F.S.

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 state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Agency for Health Care Administration has the necessary rulemaking authority to carry out the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Article I, s. 24 of the Florida Constitution and s. 119.07, F.S., both provide avenues for public records exemptions. In order to qualify for an exemption the statute must provide a public necessity statement and must meet certain public purposes. In order to clarify the legislative intent regarding the sale and lease of public hospitals, a redraft of the bill that includes a public records exemption with a rationale statement would strengthen the purpose being established by the bill.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to the sale or lease of a county,
3 district, or municipal hospital; amending s. 155.40, F.S.;
4 clarifying construction with respect to actions of a
5 lessee or purchaser; providing an effective date.
6
7 Be It Enacted by the Legislature of the State of Florida:
8
9 Section 1. Subsection (7) of section 155.40, Florida
10 Statutes, is amended to read:
11 155.40 Sale or lease of county, district, or municipal
12 hospital.--
13 (7) The lessee <u>or purchaser</u> of a hospital, pursuant to
14 this section or any special act of the Legislature, ~~operating~~
15 ~~under a lease~~ shall not be construed to be "acting on behalf of"
16 the lessor <u>or seller</u> as that term is used in statute, unless the
17 lease <u>or purchase</u> document expressly provides to the contrary.
18 Section 2. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 699 Health Care
SPONSOR(S): Negron
TIED BILLS: **IDEN./SIM. BILLS:** SB 1216

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Health Care General Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 699 amends ss. 458.331 & 459.015, F.S., to give the Allopathic (MD) and Osteopathic (DO) Medical Boards more oversight of standards involving the supervision of licensed health care practitioners.

The bill requires the Medical Boards to craft rules related to standards of practice and standards of care for supervision of physician assistants, paramedics, emergency medical technicians, advanced registered nurse practitioners, anesthesiologist assistants, and persons performing electrolysis or laser electrology who are not under direct on-sight supervision of the supervising physician. The Medical Boards may vary the rules based on specialty of the physician, type of licensed health care practitioner under supervision, and the practice setting.

The rules must include, but need not be limited to:

- The percentage of time the supervising physician spends directly supervising the licensed health care practitioners;
- Standards for adequate supervision, including the distance of the licensed health care practitioners from the supervising physician; and
- The number of each type of licensed health care practitioner which a supervising physician may supervise.

Currently, general guidelines determining supervision of the professions above are provided for by statute and administrative code.

The bill provides that the rules developed by the Medical Boards will take precedent over all other statutorily defined health care practitioner supervision provisions in chapters 458 and 459, F.S.

The full impacts of the bill, fiscal and otherwise, are difficult to determine because the bill requires the Board of Medicine to promulgate rules. Without knowing the specific rules to be promulgated, it is impossible to determine the impact.

Concerns have been raised that rulemaking authority provided in the bill may not meet the standards of ch. 120, F.S., the Administrative Procedures Act. Section 120.536, F.S., requires that an agency may only adopt rules that implement or interpret the specific powers and duties granted by the enabling statute. Agencies do not have the power to adopt a rule only because it is reasonably related to the purpose of the enabling legislation. The bill grants rulemaking authority to the Board of Medicine but specifies that the rules "need not be limited to," the standards in the bill.

The effective date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill expands regulatory control by the Board of Medicine. It provides that the Board of Medicine shall establish by rule standards of practice and standards of care, including delegation to other personnel, for particular practice settings. The rules may include, but are not limited to: time of direct supervision, standards for adequate supervision, distance limitations, and the number of practitioners that physicians can supervise.

B. EFFECT OF PROPOSED CHANGES:

HB 699 amends ss. 458.331 & 459.015, F.S., to give the Allopathic (MD) and Osteopathic (DO) Medical Boards more oversight of standards involving the supervision of licensed health care practitioners.

The bill requires the Medical Boards to craft rules related to standards of practice and standards of care for supervision of several other professions when they are not under direct on-sight supervision of the supervising physician. The professions that will be affected by the bill are: physician assistants, paramedics, emergency medical technicians, advanced registered nurse practitioners, anesthesiologist assistants, and persons performing electrolysis or electrology using laser or light-based hair removal. The Medical Boards may vary the rules based on specialty of the physician, type of licensed health care practitioner under supervision, and the practice setting.

The rules must include, but are not limited to:

- The percentage of time the supervising physician spends directly supervising the licensed health care practitioners;
- Standards for adequate supervision, including the distance of the licensed health care practitioners from the supervising physician; and
- The number of each type of licensed health care practitioner which a supervising physician may supervise.

The bill provides that the rules developed by the Medical Boards will take precedent over all other statutory defined health care practitioner supervision provisions in chapters 458 and 459, F.S.

The full impact of the bill is indeterminate because the bill gives the Board of Medicine the authority to promulgate more rules in a wide variety of situations. Without knowing the exact rules to be promulgated, it is impossible to guess what potential impacts the rules will have on the health professions referenced in the bill.

The effective date of the bill is upon becoming law.

PRESENT SITUATION

Overview - the Use of Physician Extenders

ARNPs and physician assistants (PAs) are commonly referred to as "physician extenders" because they extend the ability of a physician to treat, indirectly, more patients. Physician extenders such as nurse practitioners and nurse anesthetists have become prominent health providers. Although they generally work alongside doctors, these physician extenders administer frontline medical care to patients with increasing needs for preventative care or monitoring for people with disabilities, or diseases such as diabetes or congestive heart failure. Physician extenders are more willing to go to rural or inner-city areas, to work beyond traditional office hours[1], and are able to spend additional time

[1] Gearon, C.J. "Medicine's Turf Wars." *US News & World Report.* January 31, 2005. Available online at www.usnews.com/usnews.issue/050131/health/31turf.htm.

with patients on visits.[2] ARNPs and PAs have also taken on increased responsibility in caring for seniors, especially those in nursing homes, due to a severe and growing shortage of geriatricians in the United States.[3] Rising costs of healthcare have further increased the demand for nonphysician providers, who are able to care for patients at the same or lower cost than physicians and whose services are often covered on state and private health plans.[4] Research has shown that many nonphysician providers perform at least as safely as physicians do in these expanded roles[5]; however concerns remain that nonphysicians remain carefully supervised and trained in their scope of practice.[6]

History - Ortiz v. Department of Health, Board of Medicine, 2004[7]

Recently, there has been a court challenge that relates the issue of to the Board of Medicine promulgating rules regarding physician extenders. Specifically, the Board of Medicine promulgated administrative Rule 64B8-9.009(6)(b)1.a., F.A.C., to require a surgeon in an out-patient facility to have a licensed MD or DO anesthesiologist present to supervise the administration of anesthesia by Certified Registered Nurse Anesthetists (CRNAs). Many CRNAs objected to this rule because they felt it was not fiscally prudent for a surgeon's office to employ a physician anesthesiologist to supervise and a CRNA to perform the procedure. The Board of Medicine rule prompted a court challenge in Ortiz v. Department of Health, Board of Medicine, 2004.[8]

The court found that the Board of Medicine's rule requiring a surgeon in an out-patient facility to have a licensed anesthesiologist present to supervise the administration of anesthesia for Level III surgery was an invalid exercise of delegated authority.

As part of the ruling, the court specifically cited s. 458.303, F.S., as limiting the reach of s. 458.331, F.S. Pursuant to s. 458.303(2), F.S., the grant of rulemaking under s. 458.309, F.S., and s. 458.331, F.S., cannot be, "construed to prohibit any service rendered by a registered nurse or a licensed practical nurse, if such service is rendered under the direct supervision and control of a licensed nurse, if such service is rendered under the direct supervision and control of a licensed physician who provides specific direction for any service to be performed and gives final approval to all services performed."

Thus, the court found that under ss. 458.331 and 458.303(2), F.S., as long as a licensed physician has direct supervision and control over the registered nurse, the fact that services are provided by that nurse cannot be a ground for discipline of the physician, and no rules can prohibit such services by a registered nurse.

The Board claimed that its rule did not control the actions of CRNAs, but the court found that the rule indirectly limited the practice of CRNAs. Instead of simply prohibiting CRNAs from administering anesthesia under supervision of the surgeon, the Board provided grounds for disciplining the surgeon if he or she supervises the CRNA. Either way, currently, s. 458.303(2), F.S., prevents the use of rulemaking authority for this purpose.

The Ortiz decision noted that both parties agreed that patient safety was not an issue in the proceedings.

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[2] "Extend your practice—not your liability." *Medical Economics*. February 18, 2005.
[3] Oliff, L. "Beyond Asking Your Doctor." *Pharmaceutical Executive* 24 no2 102, 104 F 2004.
[4] Hooker, S.H., and McCaig, L.F. "Use of physician assistants and nurse practitioners in primary care, 1995-1999." *Health Affairs*. July/August 2001.
[5] According to Linda Aiken, director of the University of Pennsylvania's Center for Health Outcomes and Policy Research, over 100 studies have examined the care delivered by nurse practitioners and none demonstrated a negative impact of their care on health. Quoted in "Medicine's Turf Wars." *US News & World Report.* January 31, 2005. Available online at www.usnews.com/usnews.issue/050131/health/31turf.htm.
[6] Robert Wise, vice president for standards and survey methods at the Joint Commission on Accreditation of Healthcare Organizations, quoted in Gearon, C.J. "Medicine's Turf Wars." *US News & World Report.* January 31, 2005. Available online at www.usnews.com/usnews.issue/050131/health/31turf.htm.
[7] See *Ortiz*.
[8] See *Ortiz*.

SUPERVISION STANDARDS

The health care professionals referenced in the bill are all regulated differently by statute and rule and have varied supervisory relationships with physicians.

Supervision Standards for Advanced Registered Nurse Practitioners

Nurses are regulated in their own practice act. Nurses are licensed and regulated by the Board of Nursing pursuant to part I of chapter 464, F.S. There are approximately 9,500 Advanced Registered Nurse Practitioners (ARNPs) in Florida.

ARNPs practice under a protocol with a supervising physician and are not required to be under direct supervision. There is no limit on the number of ARNPs that a physician may supervise at any one time. ARNPs may practice in locations without the supervising physician on premises.[9] A 2005 Florida Board of Nursing study determined that 90% of nursing protocols have one physician supervising one or two ARNPS. The study also concluded that less that 2% of nurse protocols have one physician supervising four or more ARNPs. Almost all, 99%, of the ARNPs and supervising physicians are located within the same metropolitan area (roughly a 50-mile radius of an urban center).[10]

ARNPs perform medical acts of diagnosis, treatment, and operation pursuant to a protocol between the ARNP and a Florida-licensed medical doctor, osteopathic physician, or dentist. The degree and method of supervision is determined by the ARNP and the supervisor, must be appropriate for prudent health care providers under similar circumstances, and must be specifically identified in a written protocol. Unless these rules set a different level of supervision for a particular act, general supervision is required.[11] The number of ARNPs to be supervised must be limited to insure that an acceptable standard of medical care is rendered in consideration of: risk to patient, educational preparation, specialty, and experience of parties to the protocol, complexity and risk of the procedures, practice setting, and availability of the supervisor.

Supervision Standards for Anesthesiologist Assistants (a form of specialty nursing)

Anesthesiologist Assistants or Certified Registered Nurse Anesthesiologists (CRNAs) are a specialized form of Advanced Registered Nurse Practitioner that requires a masters degree. CRNAs are licensed under part I of the Nurse Practice Act, chapter 464, F.S. Every CRNA must enter into a supervisory relationship with a physician or dentist; and must file a written protocol describing the relationship based on criteria set forth in chapters 458, 459, and 466, F.S. The supervising physician must only delegate tasks and procedures to the CRNA which are within the supervising physician's scope of practice, and the CRNAs can work in any setting that is within the scope of practice of the supervisor's practice. CRNAS personally administer 65% of all anesthetics given to patients each year in the United States.[12]

Under facility licensure requirements of s. 395.0191, F.S., CRNAs working in ambulatory surgery centers or hospitals must be supervised by a physician or a dentist.

Supervision Standards for Paramedics & Emergency Medical Technicians

Paramedics and emergency medical technicians are regulated under ch. 401, F.S., Medical Transportation and Services. They are also referenced in s. 458.348, F.S. There are approximately 18,000 paramedics and 28,000 emergency medical technicians (EMTs) in Florida. Each paramedic and EMT employed within an Emergency Medical Services (EMS) system must operate under the direct supervision of a physician medical director, or indirectly by standing orders and/or protocols.[13] Each EMS agency employs or contracts with a physician medical director to provide this medical oversight

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[9] Rule 64B8-35, Florida Administrative Code.
[10] Florida Board of Nursing, Study of ARNP Protocols, November 1, 2005.
[11] The written protocol signed by all parties represents the mutual agreement of the supervising physician and the ARNP and must include information defined by Rule 64B9-4, Florida Administrative Code, and s. 458.348(2), F.S.
[12] American Association of Nurse Anesthetists, 2006.
[13] Chapter 64E-2, Florida Administrative Code.

and quality assurance. The larger EMS providers in Florida have over 1,000 EMTs and paramedics on staff, all of them working under one medical director.

Medical directors must supervise and assume direct responsibility for the medical performance of the EMTs and paramedics, and must perform duties including advising, consulting, training, counseling, and overseeing of services. This includes appropriate quality assurance but does not include administrative or managerial functions. Each medical director is required to establish a quality assurance committee to provide reviews of all EMTs and paramedics operating under the director's supervision.[14]

The Emergency Medical Services Advisory Council was created for the purpose of acting as the advisory body to the EMS program. The Council's role includes:

- Identify and make recommendations to the Department of Health (DOH) concerning the appropriateness of suggested changes to statute and administrative rules; and
- To provide technical support to DOH in the areas of EMS and trauma systems design, technology, drugs and dosages, medical protocols, training requirements, and other aspects of procedure.[15]

The Division of Emergency Medical Operations has noted that limiting the number of allied health practitioners that can practice under the authority of a single physician could potentially significantly impact the daily operations of an EMS service. According to the Division, while the implementation of the bill alone would not directly impact the EMS community, the rule language required by the bill may have a tremendous impact on the way EMS is designed and operated statewide.

Supervision Standards for Physician Assistants

Physician assistants (PAs) are regulated under ss. 458.347 & 459.022, F.S. There are approximately 3,000 licensed PAs in Florida. PAs may practice under the direct or indirect supervision of an MD or DO. A physician may supervise up to four PAs at any one time and the supervising physician must be qualified in the medical treatment areas delegated to a PA.[16] The "primary supervising physician" assumes responsibility and legal liability for the services rendered by the PAs at all times. "Direct supervision" entails the physical presence of the supervising physician on the premises so that he or she is immediately available to the PA when needed. "Indirect supervision" requires reasonable proximity between the supervising physician and the PA and requires the ability to communicate by telecommunications.[17]

There is a Council on Physician Assistants that reports to the Board of Medicine. The Council's duties include:

- Recommendation of the licensure of PAs to the Department of Health (DOH); and
- Development of rules regulating the use of PAs by physicians (proposed rules submitted by the council must be approved by both medical and osteopathic boards).

The council is comprised of five members including three physicians appointed by the chairperson of the Board of Medicine, one physician appointed by the chairperson of the Board of Osteopathic

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[14] Section 401.265, F.S

[15] Section 401.245, F.S. The council has up to 15 members, and representatives include physicians, EMS administrators, paramedics, EMTs, emergency nurse, hospital administrators, air ambulance service representatives, educators, and laypersons who are in no way connected with emergency medical services and one of whom is a representative of the elderly. Ex officio members of the advisory council from state agencies include, but are not limited to, representatives from the Department of Education, the Department of Management Services, the State Fire Marshal, the Department of Highway Safety and Motor Vehicles, the Department of Transportation, and the Department of Community Affairs.

[16] Sections 458.347 and 459.022, F.S.

[17] Rules for Medical Practice, Chapter 64B8-30, Florida Administrative Code; Rules for Osteopathic Medicine, Chapter 64B15-6, Florida Administrative Code.

Medicine, and a PA appointed by the secretary of the department or his or her designee. At least two of the members appointed to the council must be physicians who supervise PAs in their practice.[18]

Disciplinary Procedures

Disciplinary procedures for health professions vary in practice and procedures. Nurses (ARNPs and CRNAs) are disciplined directly under Chapter 464, F.S., the Nurse Practice Act, whereas, emergency personnel and PAs are disciplined by a mixed member council. The commonality is that all of the health professions have at least one peer that is included in disciplinary and regulatory proceedings.

Disciplinary Actions for Nursing

Currently RNs and LPNs may be directly disciplined under s. 464.018, F.S. One of the disciplinary criteria is, "failing to meet minimal standards of acceptable and prevailing nursing practice, including engaging in acts for which the licensee is not qualified by training or experience." Nurses can also be disciplined for violating any of the Nurse Practice Act (chapter 464), the Health Professions and Occupations: General Provisions (chapter 456, F.S.), or rules adopted by the Board of Nursing.

Disciplinary Actions for Doctors

Section 458.331(1)(v), F.S., provides ground for discipline of MDs who practice beyond the scope permitted by law or perform any procedure that he or she is not competent to perform. This section also provides that the Board of Medicine may establish rules for standards of practice and standards of care for particular practice settings including delegating to other professions.

Joint Committee of the Boards of Nursing and Medicine

In s. 464.003, F.S, the Legislature created a joint committee of the Boards of Nursing and Medicine to develop rules concerning protocols and supervision of ARNPs and other advanced specialty nurses. According to the Department of Health, HB 699 makes possible rulemaking by the Board of Medicine which may restrict the practice of nursing through threatened discipline of physicians who supervise nurses. DOH asserts that this rulemaking authority may some rulemaking authority rom the Joint Committee of the Board of Nursing and Medicine.

BACKGROUND

Scope of Practice Authority

Each year, the Florida Legislature hears bills and amendments to change the scope of practice and standards of existing professions. The legal authority to provide and be reimbursed for health care services is tied to state statutes generally referred to as practice acts, which establish professional "scopes of practice." These practice acts often differ from state to state and are a source of "turf battles" which clog the legislative agendas. Legislators must decide whether new or unregulated disciplines and occupations should be regulated and whether professions should be granted expanded practice authority. Many of the proposed changes brought to the Legislature come from professions that want to gain direct, third-party reimbursement for their services. Such changes often generate heated "turf" battles among professions and other health care interests and have potential effects on patient safety and the cost of health care.

According to the Department of Health, some physicians have raised concerns that physician extenders may economically impact sole practitioners or small practices who may not be able to compete with a practitioner who has several physician extenders located throughout a city or county.

Specialized Nursing Practice

Specialization in nursing dates from the early part of the twentieth century. Many specialty nursing programs require a master's degree and require additional state certification and licensure. Some of the primary nurse specialties are[19]:

- Critical Care;

[18] Sections 458.347 and 459.022, F.S.
[19] Nursing Health Care. 1992 May; 13(5):254-9

- Nurse Anesthetists;
- Nurse Midwives;
- Public Health Nursing; and
- Nursing Education.

There have been some concerns raised that HB 699 may limit the practice of specialty nursing if a nurse is working under a physician that does not share their specialty.

C. SECTION DIRECTORY:

Section 1. – Amends s. 458.331, F.S., to direct the Board of Medicine to promulgate rules regarding the standards of practice and standards of care for physicians who supervise licensed health care practitioners who are not under direct, onsite supervision.

Section 2. - Amends s. 459.051, F.S., to direct the Board of Osteopathic Medicine to promulgate rules regarding the standards of practice and standards of care for physicians who supervise licensed health care practitioners who are not under direct, onsite supervision.

Section 3. – Provides that the bill shall take effect upon becoming law.

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:

The direct economic impact on the private sector is indeterminate because the bill directs the Board of Medicine to develop rules regarding supervision standards of health professionals. The impact cannot be determined until the Board of Medicine promulgates the rules.

D. FISCAL COMMENTS:

HB 699 may result in an increase in health care costs in certain markets. The bill directs the Board of Medicine to promulgate stronger physician supervision rules. When promulgated, the rules may decrease the financial advantage of hiring a nurse or physician assistant to perform certain tasks and result in more direct physician care. Patient care received from a nurse or physician assistant is usually less expensive than care received by a physician.

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 state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides the necessary rulemaking authority for the Department of Health to carry out the provisions in the bill.

Concerns have been raised that rulemaking authority provided in the bill may not meet the standards of ch. 120, the Administrative Procedures Act. Section 120.536, F.S., requires that an agency may only adopt rules that implement or interpret the specific powers and duties granted by the enabling statute. Agencies do not have the power to adopt a rule only because it is reasonably related to the purpose of the enabling legislation. The bill grants rulemaking authority to the Board of Medicine but specifies that the rules "need not be limited to," the standards in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to health care; amending ss. 458.331 and
3 459.015, F.S.; requiring the Board of Medicine and the
4 Board of Osteopathic Medicine to establish by rule certain
5 standards of practice and standards of care for physicians
6 and osteopathic physicians who supervise licensed health
7 care practitioners who are not under direct, onsite
8 supervision by the supervising physician; providing an
9 effective date.
10
11 Be It Enacted by the Legislature of the State of Florida:
12
13 Section 1. Paragraph (dd) of subsection (1) of section
14 458.331, Florida Statutes, is amended to read:
15 458.331 Grounds for disciplinary action; action by the
16 board and department.--
17 (1) The following acts constitute grounds for denial of a
18 license or disciplinary action, as specified in s. 456.072(2):
19 (dd) Failing to supervise adequately the activities of
20 those physician assistants, paramedics, emergency medical
21 technicians, advanced registered nurse practitioners, or
22 anesthesiologist assistants acting under the supervision of the
23 physician. <u>Notwithstanding any other provision of this chapter,</u>
24 <u>the board shall establish by rule standards of practice and</u>
25 <u>standards of care for physicians who supervise licensed health</u>
26 <u>care practitioners who are not under direct, onsite supervision</u>
27 <u>of the supervising physician. The standards established in the</u>
28 <u>rules may vary depending on the specialty of the physician, the</u>

29 type of licensed health care practitioner under supervision, and
30 the practice setting. The rules must include, but need not be
31 limited to, the percentage of time the supervising physician
32 spends directly supervising the licensed health care
33 practitioners; standards for adequate supervision, including the
34 distance of the licensed health care practitioner from the
35 supervising physician; and the number of each type of licensed
36 health care practitioner which a supervising physician may
37 supervise.
38 Section 2. Paragraph (hh) of subsection (1) of section
39 459.015, Florida Statutes, is amended to read:
40 459.015 Grounds for disciplinary action; action by the
41 board and department.--
42 (1) The following acts constitute grounds for denial of a
43 license or disciplinary action, as specified in s. 456.072(2):
44 (hh) Failing to supervise adequately the activities of
45 those physician assistants, paramedics, emergency medical
46 technicians, advanced registered nurse practitioners,
47 anesthesiologist assistants, or other persons acting under the
48 supervision of the osteopathic physician. Notwithstanding any
49 other provision of this chapter, the board shall establish by
50 rule standards of practice and standards of care for osteopathic
51 physicians who supervise licensed health care practitioners who
52 are not under direct, onsite supervision of the supervising
53 osteopathic physician. The standards established in the rules
54 may vary depending on the specialty of the physician, the type
55 of licensed health care practitioner under supervision, and the
56 practice setting. The rules must include, but need not be

57 limited to, the percentage of time the supervising osteopathic
58 physician spends directly supervising the licensed health care
59 practitioners; standards for adequate supervision, including the
60 distance of the licensed health care practitioner from the
61 supervising osteopathic physician; and the number of each type
62 of licensed health care practitioner which a supervising
63 osteopathic physician may supervise.
64 Section 3. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 747 Health Professionals Treating Speech or Hearing Disorders
SPONSOR(S): Greenstein
TIED BILLS: **IDEN./SIM. BILLS:** SB 370

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 747 revises the requirements for Department of Health's Board of Speech-Language Pathology and Audiology to issue licenses and provisional licenses to practice as a speech-language pathologist or audiologist in Florida.

Frequent changes in the academic and clinical requirements for accreditation have led to the need for revisions to Florida's practice act for speech-language pathology and audiology. Speech-language pathology programs require a master's entry-level for clinical practice with expanded knowledge and skills and competency-based assessment as of January 1, 2005. Currently, the programs in Florida that are offering master's degrees in speech-language pathology meet these new expanded standards. By January 1, 2007, the audiology profession in Florida will transition to expanded educational requirements and requirement of a doctoral degree.

The bill provides that applicants requesting a provisional license as a speech-language pathologist or audiologist must meet certain requirements in the areas of academic course work, practicum experience, and supervised clinical experience or professional employment. The bill also revises the licensure requirements for foreign trained or out-of-state applicants.

The bill requires applicants requesting licensure as an audiologist to have a minimum of 11 months of full-time professional employment. Currently, speech-language pathologists and audiologists must have 9 months of full-time professional employment. The bill provides that the board may certify an audiologist for licensure if the applicant has obtained a doctoral degree in audiology, and satisfied the supervised clinical requirements and professional education requirements. Currently, an audiologist is not required to possess a doctoral degree in audiology, but is required to pass an examination which will no longer be required if they have a doctoral degree.

The bill requires a speech-language assistant or audiology assistant to have a plan for on-the-job training and decreases the educational requirements for audiology assistants. An audiologist or speech-language pathologist, who employs an assistant, is responsible for all the services performed by the assistant.

Fiscal Impact: According to the Department of Health, if the board is required to determine equivalency of training for foreign trained applicants the department will incur costs to translate transcripts and to hire education program experts to determine program equivalency which may increase or generate litigation issues.

The bill takes effect July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-The bill requires the Department of Health to determine the equivalency of education for foreign trained health professionals requesting a license or provisional license to practice as a speech-language pathologist or audiologist in Florida. Determining equivalency may also increase litigation cases for the department.

B. EFFECT OF PROPOSED CHANGES:

The bill revises the requirements for Department of Health's Board of Speech-Language Pathology and Audiology to issue licenses and provisional licenses to practice as a speech-language pathologist and audiologist.

Changes to the Professional Training Requirements for Speech-Language Pathology and Audiology

Frequent changes in the academic and clinical requirements for accreditation have led to the need for revisions to Florida's practice act for speech-language pathology and audiology. In 1997, the profession of Speech Language Pathology and Audiology became regulated. The Educational Testing Service completed national skills validation studies for both professions and concluded that the knowledge and skills of practitioners must be expanded to assure good quality care to the persons both professions serve.

Florida universities were the first in the nation to transition all accredited university training programs to the Doctor of Audiology degree. The University of Florida (UF), University of South Florida (USF), and Nova Southeastern University are the only universities in Florida with audiology programs and each offer the Doctor of Audiology degree.

By January 1, 2007, the audiology profession in Florida will transition to expanded educational requirements and requirement of a doctoral degree.

Speech-language pathology will remain at the master's entry-level for clinical practice, also with expanded knowledge and skills and competency-based assessment as of January 1, 2005. Speech-language pathology master's degree programs in Florida currently meet the expanded standards that became effective on January 1, 2005.

The Bill Makes Changes to the Practice Act for Speech-Language Pathology and Audiology

The bill changes requirements for licensure for speech-language pathologist and audiologist to increase the educational standards so that they are concurrent with the national trends that are and will continue to evolve over the next several years.

The bill replaces the requirements for specified hours of course work and clinical experience with requirements for specific areas of knowledge and skills that are appropriate to completed accredited degree programs. The bill revises the requirements for licensure by endorsement, provisional licenses, provisional licensure for foreign trained professionals, and certification of speech-language pathology assistants and audiology assistants.

The bill increases the educational requirements for licensure in audiology to a doctoral degree in audiology. A transition period is provided to master degree recipients so they may qualify for a provisional license, which is good for 24 months, until they meet the higher educational requirements of

a doctoral degree in audiology. The bill provides that if an applicant requests licensure as an audiologist and has met the supervised clinical requirements, professional education requirements, and has earned a doctoral degree in audiology they are not required to pass the licensure examination.

Effective January 1, 2008, an audiologist who has earned a master's degree in a program with a major emphasis in audiology or earned a doctoral degree in audiology but not passed the license examination is eligible to receive a provisional license.

Until January 1, 2013, the board may waive the education, practicum, and professional employment requirements of foreign trained provisional licensure applicants, if the board is satisfied that an applicant meets the equivalency requirements and passes the examination in speech-language pathology or audiology.

Currently, speech-language pathologists and audiologists must have 9 months of full-time professional employment prior to licensure.[1] The bill requires applicants requesting licensure as an audiologist to have a minimum of 11 months of full-time professional employment.

The bill provides language that broadens the recognition of accredited schools or institutions of higher learning, to include schools that are accredited by the US Department of Education or a successor to the Council for Higher Education Accreditation.

The bill decreases the educational requirements for audiology assistants by removing the 24 semester hours of course work required for certification and specifies that audiology assistants must possess at least a high school diploma or its equivalent.

The bill requires an audiologist or speech-language pathologist to provide their assistants with a work plan approved by the board for on-the-job training. An audiologist or speech-language pathologist, who employs an assistant, is responsible for all the services performed by the assistant.

BACKGROUND INFORMATION

In 1995, approximately 46 million people in the United States of all ages, races and gender, experienced or lived with some type of communication disorder.[2] According to the American Speech-Language Hearing Association, 28 million individuals have a hearing loss.[3]

Audiologists, speech-language pathologists, and speech, language, and hearing scientists are professionals who evaluate, treat, and conduct research into human communication and its disorders.

Speech and language disorders are inabilities of individuals to understand and/or appropriately use the speech and language systems of society. Such disorders may range from simple sound repetitions or occasional misarticulations to the complete absence of the ability to use speech and language for communication.

National Certification by the American Speech-Language and Hearing Association

The American Speech-Language Hearing Association provides voluntary certification for speech-language pathologists and audiologists. In 1997, the American Board for Audiology was founded to provide voluntary board certification for audiologists.

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[1] See s. 468.1165, F.S.

[2] American Speech-Language Pathology Association, *Speech-Language Disorders and the Speech-Language Pathologist*, http://www.asha.org/students/professions/overview/sld.htm

[3] A Decade of Progress Ahead. *1990 Annual Report of the National Deafness and Other Communication Disorders Advisory Board.* http://www.asha.org/students/professions/overview/hla.htm

American Speech-Language Hearing Association Requirements for the Certificate of Clinical Competence

Applicants for the American Speech-Language Hearing Association Certificate of Clinical Competence (C.C.C.) must have a master's or a doctoral degree. Candidates for certification must have completed at least 27 semester credit hours in basic science course work; 36 semester credit hours in professional coursework; 375 Clock Hours of Supervised Clinical Observation/Practice; a clinical fellowship that encompasses 36 weeks of full-time professional experience; and successfully pass the national examination.

American Speech-Language Hearing Association Requirements for Certification in Audiology

Demonstration of continued professional development is mandated for maintenance of the Certificate of Clinical Competence in Audiology. This standard took effect on January 1, 2003. The certification is good for three years. The new professional development standard will apply to all certificate holders, regardless of the date of initial certification. Individuals who hold the Certificate of Clinical Competence in Audiology must accumulate 30 contact hours of professional development over the 3-year period in order to meet this standard.[4]

C. SECTION DIRECTORY:

Section 1. Amends s. 468.1155, F.S., to revise the requirements of issuing provisional licenses to speech-language pathologists and audiologists.
Section 2. Amends s. 468.1165, F.S., to increase the time requirement for professional employment experience.
Section 3. Amends s. 468.1185, F.S., to revise requirements to issue a license to an applicant to practice audiology.
Section 4. Amends s. 468.1215, F.S., to revise the on-the-job training requirements by requiring a work plan for speech-language pathology assistants and audiology assistants; removes the college coursework requirements for audiology assistants and requires them to have at least a high school diploma or its equivalent.
Section 5. Provides the bill will take effect July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See "D. Fiscal Comments"

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

[4] American Speech-Language Pathology Association, *Certification Maintenance Guidelines for Audiology*, http://www.asha.org/about/membership-certification/certification/standard6_aud_guide.htm

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There may be costs associated with the additional education requirement. The practitioners will be better educated to provide the appropriate care.

D. FISCAL COMMENTS:

According to the Department of Health, if the board is required to determine equivalency of training for foreign trained applicants there may be a cost associated with translations of transcripts and the hiring of education program experts to determine program equivalency. These costs can be reduced or eliminated by allowing the board to rely on professional credentials review organizations. There may be an increase in litigation due to the equivalency determination required of the board. Nearly every foreign educated speech–language pathologist or audiologist who is denied a license will litigate with the board over the correctness of the denial.

According to DOH, the department may incur minimal costs relating to rulemaking under the bill. The board will also need to update the licensure application to include the acceptance of the American Board of Audiology certification for applicants seeking licensure by endorsement to practice as an audiologist in Florida.

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 an 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 revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Board of Speech-Language Pathology and Audiology the authority required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

DRAFTING ISSUES:
On page 9, line 241, the bill reads:

<u>subparagraph (2)(b)2.</u>

There is not a subparagraph to subsection (2)(b) in s. 468.1185, F.S. It appears there is a drafting error that should be corrected.

OTHER COMMENTS:
The Board of Speech-Language Pathology and Audiology created a review panel to look at any needed changes to the current statutory provisions, specifically focusing on educational standards. The intent of the recommendations from this panel and the board as a whole are encompassed in this bill.

According to the board, the intent of the language is to provide the board with authority to increase the educational standards concurrent with the national trends that are and will continue to evolve over the

next several years. These changes include requiring more education and clinical experience prior to licensure, but are significantly delayed by Section 1(3)(c) of the bill. This section deals with the provisional licensure for applicants who have earned a master's degree with a major emphasis in audiology and provides a grandfather clause for them until January 2008 or January 2013 for foreign trained applicants.

Litigation Concerns in Determining Foreign Trained Education Equivalency

According to DOH, the bill may increase or generate litigation issues. Nearly every foreign educated speech–language pathologist or audiologist who is denied a license will litigate with the board over the correctness of the denial. Board members will have to become education program experts and will have to hire educational program experts to determine whether the applicant "meets the equivalent" education and practicum requirements. Similarly there will be litigation over when and whether the board should "waive" the education, practicum, and professional employment experience because the applicant obtained "the equivalent" elsewhere. Board members also lack the ability to translate foreign transcripts from all over the world so they will have to have the documentation translated into English.

According to the department, currently, foreign trained applicants must present documentation of the determination of equivalency by the Council for Higher Education in order to qualify for a provisional license.

The board indicated that the determination of equivalency should be made by the credentialing experts who report to the board but are paid for by the applicants as is the case in other professions.

The board states that allowing them to rely on the expert opinions of a professional credential review company that can evaluate the educational background of foreign graduates might discourage or limit some of the litigation.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to health professionals treating speech or
3 hearing disorders; amending s. 468.1155, F.S.; revising
4 requirements for the Department of Health in issuing a
5 provisional license to practice speech-language pathology
6 or audiology; revising licensing requirements for
7 applicants who graduated or are currently enrolled in a
8 speech-language pathology or audiology program at a
9 university located outside of the United States or Canada;
10 authorizing the Board of Speech-Language Pathology and
11 Audiology to waive certain requirements for applicants who
12 received professional education in another country under
13 certain circumstances; amending s. 468.1165, F.S.;
14 revising requirements for applicants to obtain
15 professional employment in order to be licensed by the
16 department to practice speech-language pathology or
17 audiology; amending s. 468.1185, F.S.; revising
18 requirements for the department to issue a license to an
19 applicant to practice speech-language pathology or
20 audiology; amending s. 468.1215, F.S.; revising
21 requirements for a person to be certified as an audiology
22 assistant; requiring an audiologist or speech-language
23 pathologist to give an assistant a board-approved plan for
24 training and to maintain responsibility for services
25 performed by the assistant; providing an effective date.
26
27 Be It Enacted by the Legislature of the State of Florida:
28

29 Section 1. Section 468.1155, Florida Statutes, is amended
30 to read:
31 468.1155 Provisional license; requirements.--
32 (1)(a) A provisional license shall be required of all
33 applicants for a license in speech-language pathology who cannot
34 document a minimum of 9 months of supervised professional
35 employment experience and a passing score on the national
36 examination. A provisional license shall be required of all
37 applicants for a license in audiology who cannot document a
38 minimum of 11 months of supervised clinical experience and a
39 passing score on the national examination.
40 (b) Individuals who are required to hold a provisional
41 license under paragraph (a) shall apply to the department and be
42 certified by the board for licensure prior to initiating the
43 professional employment experience required pursuant to s.
44 468.1165.
45 (2) The department shall issue a provisional license to
46 practice speech-language pathology to each applicant who the
47 board certifies has:
48 (a) Completed the application form and remitted the
49 required fees, including a nonrefundable application fee.
50 (b) Received a master's degree or completed the academic
51 requirement of ~~is currently enrolled in~~ a doctoral degree
52 program with a major emphasis in speech-language pathology from
53 an institution of higher learning that ~~which~~ is, or at the time
54 the applicant was enrolled and graduated was, accredited by an
55 accrediting agency recognized by the Council for Higher
56 Education Accreditation or its successor or the United States

57 Department of Education or from an institution that ~~which~~ is a
58 member in good standing with the Association of Universities and
59 Colleges of Canada. An applicant who graduated from or is
60 currently enrolled in a program at a university or college
61 outside the United States or Canada must present documentation
62 of the determination of equivalency of the program to standards
63 established by an accrediting body recognized by the Council for
64 Higher Education Accreditation or its successor or the United
65 States Department of Education in order to qualify.
66 1. The applicant must have completed the program
67 requirements by academic course work, practicum experience, or
68 laboratory or research activity, as verified by the program,
69 including:
70 a. Knowledge of basic human communication and swallowing
71 processes, including their biological, neurological, acoustic,
72 psychological, developmental, and linguistic and cultural bases.
73 b. Knowledge of the nature of speech, language, hearing,
74 and communication disorders and differences and swallowing
75 disorders, including their etiologies; anatomical or
76 physiological characteristics; acoustic, psychological,
77 developmental, and linguistic and cultural correlates; voice and
78 resonance, including respiration and phonation; receptive and
79 expressive language in speaking, listening, reading, writing,
80 and manual modalities; hearing, including the impact on speech
81 and language; swallowing; cognitive aspects of communication;
82 social aspects of communication; and communication modalities.
83 c. Knowledge of the principles and methods of prevention,
84 assessment, and intervention for people having communication and

85 swallowing disorders, including consideration of anatomical or
86 physiological, psychological, developmental, and linguistic and
87 cultural correlates of the disorders, articulation, fluency,
88 voice and resonance, receptive and expressive communication,
89 hearing, swallowing, cognitive aspects of communication, social
90 aspects of communication, and communication modalities.
91 2. The program must include appropriate supervised
92 clinical experiences.
93
94 The board may waive the requirements for education, practicum,
95 and professional employment experience for an applicant who
96 received a professional education in another country if the
97 board is satisfied that the applicant meets the equivalent
98 education and practicum requirements and passes the examination
99 in speech-language pathology. ~~60 semester hours that include:~~
100 ~~1. Fundamental information applicable to the normal~~
101 ~~development and use of speech, hearing, and language;~~
102 ~~information about training in management of speech, hearing, and~~
103 ~~language disorders; and information supplementary to these~~
104 ~~fields.~~
105 ~~2. Six semester hours in audiology.~~
106 ~~3. Thirty of the required 60 semester hours in courses~~
107 ~~acceptable toward a graduate degree by the college or university~~
108 ~~in which these courses were taken, of which 24 semester hours~~
109 ~~must be in speech-language pathology.~~
110 ~~(c) Completed 300 supervised clinical clock hours with 200~~
111 ~~clock hours in the area of speech-language pathology or~~
112 ~~completed the number of clock hours required by an accredited~~

113 ~~institution meeting national certification standards. The~~
114 ~~supervised clinical clock hours shall be completed within the~~
115 ~~training institution or one of its cooperating programs.~~
116 (3) The department shall issue a provisional license to
117 practice audiology to each applicant who the board certifies
118 has:
119 (a) Completed the application form and remitted the
120 required fees, including a nonrefundable application fee.
121 (b) Effective January 1, 2008, earned a doctoral degree in
122 audiology, but has not passed the license examination required
123 for a license in audiology or has completed the academic
124 requirements of ~~Received a master's degree or is currently~~
125 ~~enrolled in~~ a doctoral degree program with a major emphasis in
126 audiology from an institution of higher learning that ~~which~~ is,
127 or at the time the applicant was enrolled and graduated was,
128 accredited by an accrediting agency recognized by the Council
129 for Higher Education Accreditation or its successor or the
130 United States Department of Education or from an institution
131 that ~~which~~ is a member in good standing with the Association of
132 Universities and Colleges of Canada. An applicant who graduated
133 from or is currently enrolled in a program at a university or
134 college outside the United States or Canada must present
135 documentation of the determination of equivalency of the program
136 to standards established by an accrediting body recognized by
137 the Council for Higher Education Accreditation or its successor
138 or the United States Department of Education in order to
139 qualify.
140 1. The program must ensure that the student obtained

141 knowledge of foundation areas of basic body systems and
142 processes related to hearing and balance.
143 2. The program must ensure that the student obtained
144 skills for the diagnosis, management, and treatment of auditory
145 and vestibular or balance conditions and diseases.
146 3. The program must ensure that the student can
147 effectively communicate with patients and other health care
148 professionals.
149 4. The program must ensure that the student obtained
150 knowledge of professional ethical systems as they relate to the
151 practice of audiology.
152 5. The program must ensure that the student obtained
153 clinical experiences that encompass the entire scope of practice
154 and focus on the most current evidence-based practice.
155
156 The board may waive the education, practicum, and professional
157 employment experience requirements for an applicant who received
158 a professional education in another country if the board is
159 satisfied that the applicant meets equivalent education and
160 practicum requirements and passes the examination in audiology.
161 (c) Has earned a master's degree with a major emphasis in
162 audiology which was conferred before January 1, 2008, from an
163 institution of higher learning which was, or at the time the
164 applicant was enrolled and graduated, accredited by an
165 accrediting agency recognized by the Council for Higher
166 Education Accreditation or its successor or the United States
167 Department of Education or from an institution that is a member
168 in good standing with the Association of Universities and

169 Colleges of Canada.
170 1. An applicant who graduated from or is currently
171 enrolled in a program at a university or college outside the
172 United States or Canada must present documentation of the
173 determination of equivalency of the program to standards
174 established by an accrediting body recognized by the Council for
175 Higher Education Accreditation or its successor or the United
176 States Department of Education in order to qualify.
177 2. The board may waive the education, practicum, and
178 professional employment experience requirements for an applicant
179 who received a professional education in another country if the
180 board is satisfied that the applicant meets equivalent education
181 and practicum requirements and passes the examination in
182 audiology. This paragraph expires January 1, 2013. ~~The applicant~~
183 ~~must have completed 60 semester hours that include:~~
184 ~~1. Fundamental information applicable to the normal~~
185 ~~development and use of speech, hearing, and language;~~
186 ~~information about training in management of speech, hearing, and~~
187 ~~language disorders; and information supplementary to these~~
188 ~~fields.~~
189 ~~2. Six semester hours in speech-language pathology.~~
190 ~~3. Thirty of the required 60 semester hours in courses~~
191 ~~acceptable toward a graduate degree by the college or university~~
192 ~~in which these courses were taken, of which 24 semester hours~~
193 ~~must be in audiology.~~
194 ~~(c) Completed 300 supervised clinical clock hours with 200~~
195 ~~clock hours in the area of audiology or completed the number of~~
196 ~~clock hours required by an accredited institution meeting~~

197 ~~national certification standards. The supervised clinical clock~~
198 ~~hours shall be completed within the training institution or one~~
199 ~~of its cooperating programs.~~
200 ~~(4) An applicant who has received a master's degree or is~~
201 ~~currently enrolled in a doctoral degree program with a major~~
202 ~~emphasis in speech-language pathology as provided in subsection~~
203 ~~(2), or audiology as provided in subsection (3), and who seeks~~
204 ~~licensure in the area in which the applicant is not currently~~
205 ~~licensed, must have completed 30 semester hours in courses~~
206 ~~acceptable toward a graduate degree and 200 supervised clinical~~
207 ~~clock hours in the second discipline from an accredited~~
208 ~~institution.~~
209 (4) ~~(5)~~ The board, by rule, shall establish requirements
210 for the renewal of a provisional license. However, a provisional
211 license may not exceed a period of 24 months.
212 Section 2. Section 468.1165, Florida Statutes, is amended
213 to read:
214 468.1165 Professional employment experience
215 requirement.--Every applicant for licensure as a speech-language
216 ~~speech~~ pathologist must ~~or audiologist shall~~ demonstrate, prior
217 to licensure, a minimum of 9 months of full-time professional
218 employment~~,~~ or the equivalent in part-time professional
219 employment~~, pertinent to the license being sought~~. Each
220 applicant for licensure as an audiologist must demonstrate,
221 prior to licensure, a minimum of 11 months of full-time
222 professional employment or the equivalent in part-time
223 professional employment. The board, by rule, shall establish
224 standards for obtaining and verifying the required professional

225 employment experience.
226 Section 3. Subsections (2) and (3) of section 468.1185,
227 Florida Statutes, are amended to read:
228 468.1185 Licensure.--
229 (2)(a) The board shall certify for licensure any applicant
230 who has:
231 1.~~(a)~~ Satisfied the education and supervised clinical
232 ~~clock hour~~ requirements of s. 468.1155.
233 2.~~(b)~~ Satisfied the professional experience requirement of
234 s. 468.1165.
235 3.~~(c)~~ Passed the licensure examination required by s.
236 468.1175.
237 (b) An applicant for an audiologist license who has
238 obtained a doctoral degree in audiology has satisfied the
239 education and supervised clinical requirements of subparagraph
240 (2)(a)1. and the professional experience requirements of
241 subparagraph (2)(b)2.
242 (3) The board shall certify as qualified for a license by
243 endorsement as a speech-language pathologist or audiologist an
244 applicant who:
245 (a) Holds a valid license or certificate in another state
246 or territory of the United States to practice the profession for
247 which the application for licensure is made, if the criteria for
248 issuance of such license were substantially equivalent to or
249 more stringent than the licensure criteria which existed in this
250 state at the time the license was issued; or
251 (b) Holds a valid ~~Has received the~~ certificate of clinical
252 competence of the American Speech-Language and Hearing

253 Association or board certification in audiology from the
254 American Board of Audiology.
255 Section 4. Subsections (2), (3), and (4) of section
256 468.1215, Florida Statutes, are amended to read:
257 468.1215 Speech-language pathology assistant and audiology
258 assistant; certification.--
259 (2) The department shall issue a certificate as an
260 audiology assistant to each applicant who the board certifies
261 has:
262 (a) Completed the application form and remitted the
263 required fees, including a nonrefundable application fee.
264 (b) Earned a high school diploma or its equivalent.
265 ~~Completed at least 24 semester hours of coursework as approved~~
266 ~~by the board at an institution accredited by an accrediting~~
267 ~~agency recognized by the Council for Higher Education~~
268 ~~Accreditation.~~
269 (3) An audiologist or speech-language pathologist who
270 employs a speech-language assistant or audiology assistant must
271 provide the assistant with a plan approved by the board for on-
272 the-job training and must maintain responsibility for all
273 services performed by the assistant. The board, by rule, shall
274 establish minimum education and on-the-job training and
275 supervision requirements for certification as a speech-language
276 pathology assistant or audiology assistant.
277 (4) The provisions of this section shall not apply to any
278 student, intern, or trainee performing speech-language pathology
279 or audiology services while completing the supervised clinical
280 experience ~~clock hours~~ as required in s. 468.1155.

281 Section 5. This act shall take effect July 1, 2006.

HB 903

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 903 Pharmacy Common Databases
SPONSOR(S): Traviesa
TIED BILLS: **IDEN./SIM. BILLS:** SB 1838

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 903 changes the way Schedule II prescription drugs are processed when transferred to another pharmacy. Schedule II prescription drugs are drugs that have high potential for abuse and may lead to psychological dependence. Currently mail-order pharmacy benefit managers (PBMs) must physically or electronically send a Schedule II prescription to their automated dispensing operation, before dispensing Schedule II prescriptions. The bill removes this regulatory step in the mail-order prescription dispensing process.

The bill creates s. 456.0266, F.S., to allow the dispensing and refilling of a prescription, including Schedule II, prescription drugs, that is on file in a pharmacy located anywhere in the United States. The bill proposes the following stipulations that must be met in order for mail-order pharmacies to transfer a prescription:

- The participating pharmacies must have the same owner and share a common database;
- The prescription information must be maintained within the common database;
- The common database must maintain a record of all persons involved, in any manner, in the dispensing or refilling of the prescription;
- All participating pharmacies must be properly licensed by their state of residence;
- All participating pharmacies in another state must be properly registered or permitted as a nonresident or Internet pharmacy in Florida; and
- All participating pharmacists are responsible for the actual task performed in the dispensing or refilling of the prescription.

It is difficult to estimate how many out of state pharmacies will register as an internet or nonresident pharmacy. If only a few nonresident or internet pharmacies register, there will be no or a very minimal fiscal impact on the Department of Health (DOH).

If a large number of nonresident and internet pharmacies register with the DOH, there will be a greater fiscal impact to DOH. More registrants will result in more disciplinary actions pursued by the DOH, and there will be additional costs associated with inspecting pharmacies, and investigating and prosecuting disciplinary violations. In order to manage the increased workload, DOH would have to hire more staff.

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government / Ensure Lower Taxes – The bill allows pharmacies that have the same owner and share a common database to dispense Schedule II prescription drugs without physically transferring the prescription from one location to another.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

The transfer of Schedule II prescriptions is currently necessary for mail order prescription drug companies. Usually a "front-end" pharmacy processes the prescription and makes several checks before sending the prescription to the "back-end" pharmacy through a common database. The "back-end" pharmacy is automated and responsible for mailing out prescriptions. Currently, Schedule II prescriptions must be sent to the back-end pharmacy even if both the pharmacies share a common owner and database.

Section 465.026(7), F.S., establishes conditions under which a community pharmacy can transfer prescriptions for drugs listed in Schedule II. Under chapter 893, F.S., Schedule II drugs are defined as drugs that have a high potential for abuse, are currently accepted for medical use in treatment in the United States, and may lead to serious psychological dependence. Codeine, morphine, and methadone are all examples of Schedule II drugs.

Section 465.026(7), F.S., outlines the transfer of a prescription verbally or by electronic means to the receiving pharmacy. The transfer procedure is outlined in ss. 465.026(1)-(5), and. 465.026(7), F.S.

Subsections 465.026(1)-(5), F.S., require that prior to dispensing any transferred prescription a number of safety precautions are taken by the pharmacist, such as:

- Specifying that the sending pharmacy must cancel their prescription order;
- Placing the responsibility for ensuring the accurate dispensing of the medication on the receiving pharmacy;
- Requiring the dispensing pharmacy to advise the patient that the prescription on file at the sending pharmacy must be canceled;
- Placing responsibility on the receiving pharmacist to exercise professional judgment in validating the transferred prescription;
- Providing that it is the responsibility of the pharmacy or pharmacist in the State of Florida to verify that the receiving pharmacy or pharmacist is properly licensed; and
- Providing special restrictions on the transfer of prescriptions for Schedule II controlled substances.

Effects of the Bill

HB 903 repeals the provisions in s. 465.026(7), F.S., which establish conditions for a pharmacy to transfer Schedule II prescription drugs.

HB 903 creates s. 456.0266, F.S., to allow the dispensing or refilling of a prescription, including Schedule II prescription drugs, that are on file in a pharmacy located in this state or in another state by

a pharmacist located in this state or in another state, without the physical transfer of prescription (postal mail) if the following criteria are met:

- The participating pharmacies have the same owner and share a common database;
- The prescription information is maintained within the common database;
- The common database maintains a record of all persons involved, in any manner, in the dispensing or refilling of the prescription;
- All participating pharmacies are properly licensed by their state of residence;
- All participating pharmacies in another state are properly registered or permitted as a nonresident or Internet pharmacy in Florida; and
- All participating pharmacists are responsible for the actual task performed in the dispensing or refilling of the prescription.

The bill allows an out-of-state pharmacist to perform all or part of the dispensing of a prescription without being licensed in Florida or being subject to regulation in Florida. Under the new provisions created in HB 903, there is no one pharmacist responsible for the filling of a prescription. A pharmacist is only responsible for the actual task performed (i.e. the counting of pills).

The effective date of the bill is July 1, 2006.

BACKGROUND

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) are companies under contract with managed care organizations, self-insured companies, and government programs to manage pharmacy network management, drug utilization review, outcomes management, and disease management. Medco, Caremark, and Express Scripts are three of the largest PBMs operating in the United States. The primary objective of the PBM is to save money. To this end PBMs generally fill drug prescriptions by mail-order as part of a corporate health insurance plan.

The "front-end" pharmacy of the mail order PBM operation usually receives prescriptions, performs pharmacist verification, and processes prescriptions through a drug utilization review. The "back-end" pharmacy usually communicates with the "front-end" pharmacy through a common database. The primary function of the "back-end" pharmacy is to perform automated prescription fulfillment functions.

C. SECTION DIRECTORY:

Section 1. – Amends s. 465.026, F.S., to repeal a provision that allows community pharmacies to transfer and dispense Schedule II prescriptions.

Section 2. – Creates s. 456.0266, F.S., to provide that pharmacies with a common database may dispense or refill a prescription on file without the physical transfer of a prescription.

Section 3. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Indeterminate.

2. Expenditures:

   Indeterminate.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill would allow pharmacists that enter Schedule II prescription drugs at one location to dispense the same drugs at a different location without transferring the physical prescription. The savings incurred by the company by skipping this step may be passed on to the customer.

D. FISCAL COMMENTS:

It is difficult to estimate how many out of state pharmacies will register as an internet or nonresident pharmacy. If only a few nonresident or internet pharmacies register, there will be no or a minimal fiscal impact on the Department of Health (DOH).

If a large number of nonresident and internet pharmacies register with the DOH, there will be a greater fiscal impact to DOH. More registrants will result in more disciplinary actions pursued by the DOH, and there will be additional costs associated with inspecting pharmacies, and investigating and prosecuting disciplinary violations. In order to manage the increased workload, DOH would have to hire more staff.

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 state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

In order for the Department of Health (DOH) to carry out the provisions in the bill, DOH would have to repeal the conflicting regulatory rules.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Federal law 21 CFR 1306.11 requires that the original hard copy prescription for a Schedule II controlled substance is maintained at the dispensing pharmacy. The proposed bill seems to allow dispensing of a Substance II drug without transferring the hard copy of the prescription to the "back-end" pharmacy.

According the federal Drug Enforcement Administration (DEA), the transfer from a "front-end" pharmacy to a "back-end" pharmacy that communicates through a common database is allowable under current regulation (federal law). The entry of prescription information into a centralized database system at one location and the ultimate dispensing of the same prescription from another location

which is owned and operated by the same company is not considered a prescription transfer by the DEA.[1]

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

[1] Letter from Drug Enforcement Administration to Merck-Medco, May 23, 2002.

1 A bill to be entitled
2 An act relating to pharmacy common databases; amending s.
3 465.026, F.S.; deleting a provision authorizing certain
4 community pharmacies to transfer prescriptions for
5 Schedule II medicinal drugs under certain conditions;
6 creating s. 465.0266, F.S.; authorizing the dispensing or
7 refilling of a prescription without a transferred
8 prescription under specified conditions; providing an
9 effective date.
10
11 Be It Enacted by the Legislature of the State of Florida:
12
13 Section 1. Subsection (7) of section 465.026, Florida
14 Statutes, is amended to read:
15 465.026 Filling of certain prescriptions.--Nothing
16 contained in this chapter shall be construed to prohibit a
17 pharmacist licensed in this state from filling or refilling a
18 valid prescription which is on file in a pharmacy located in
19 this state or in another state and has been transferred from one
20 pharmacy to another by any means, including any electronic
21 means, under the following conditions:
22 ~~(7) A community pharmacy licensed under this chapter which~~
23 ~~only receives and transfers prescriptions for dispensing by~~
24 ~~another pharmacy may transfer a prescription for a medicinal~~
25 ~~drug listed in Schedule II under chapter 893. The pharmacy~~
26 ~~receiving the prescription may ship, mail, or deliver into this~~
27 ~~state, in any manner, the dispensed Schedule II medicinal drug~~
28 ~~under the following conditions:~~

29 ~~(a) The pharmacy receiving and dispensing the transferred~~
30 ~~prescription maintains at all times a valid, unexpired license,~~
31 ~~permit, or registration to operate the pharmacy in compliance~~
32 ~~with the laws of the state in which the pharmacy is located and~~
33 ~~from which the medicinal drugs are dispensed;~~
34 ~~(b) The community pharmacy and the receiving pharmacy are~~
35 ~~owned and operated by the same person and share a centralized~~
36 ~~database; and~~
37 ~~(c) The community pharmacy assures its compliance with the~~
38 ~~federal laws and subsections (1)-(5).~~
39 Section 2. Section 465.0266, Florida Statues, is created
40 to read:
41 465.0266 Common database.--The dispensing or refilling of
42 a prescription on file in a pharmacy located in this state or in
43 another state by a pharmacist licensed in this state or in
44 another state shall not require the transfer of the prescription
45 if all of the following conditions are present:
46 (1) The participating pharmacies have the same owner and
47 share a common database.
48 (2) The prescription information is maintained within the
49 common database.
50 (3) The common database maintains a record of all persons
51 involved, in any manner, in the dispensing or refilling of the
52 prescription.
53 (4) All participating pharmacies are properly licensed by
54 their state of residence.
55 (5) All participating pharmacies in another state are
56 properly registered or permitted as a nonresident or Internet

57 pharmacy in this state.
58 (6) All participating pharmacists are responsible for the
59 actual task performed in the dispensing or refilling of the
60 prescription.
61 Section 3. This act shall take effect July 1, 2006.